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INTRODUCTION

Overview of Accreditation Programs

The College of American Pathologists (CAP) has established and currently directs multiple accreditation programs. The Laboratory Accreditation Program (LAP) was established in 1961. In 1995, it received approval as an accrediting organization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS), an agency within the US Department of Health and Human Services. The LAP offers the broadest scope of disciplines of any approved accreditation program. Additional accreditation programs have been established as follows: Forensic Drug Testing (FDT) in 1988, Reproductive Laboratory Program (RLAP) in 1993, and the Biorepository Accreditation Program (BAP) in 2011.

In 2008 the CAP established a voluntary nonregulated accreditation program with the ISO 15189:2007 Standard as published by the International Organization for Standardization. CAP 15189 requires a steadfast commitment to the laboratory management system and all interacting departments. CAP 15189 does not replace the CLIA-based Laboratory Accreditation Program, but rather complements CAP accreditation and other quality systems by optimizing processes to improve patient care, strengthen deployment of quality standards, mitigate risk, and control costs.

The four laboratory accreditation programs are all created with the primary objective of improving the quality of clinical laboratory services. The LAP, BAP, FDT, and RLAP employ voluntary participation, professional peer review, education, and compliance with established performance standards. Since their creation, these programs have become widely acknowledged for excellence. In all, the College accredits more than 7,000 laboratories.

The mission statement of the CAP Accreditation Program is:

“The CAP Accreditation Program improves patient safety by advancing the quality of pathology and laboratory services through education and standard setting, and ensuring laboratories meet or exceed regulatory requirements.”

The vision of the College is to be the world’s leader and innovator in laboratory accreditation. The CAP is the primary driver in the transformation of the specialty of pathology positioning pathologists to be in a central role in medicine and patient care. As the change agent for this transformation, the CAP will evolve to greatly strengthen its position to be:

- The leading organization guiding pathologists as they embrace emerging technologies in the new era of diagnostic medicine;
- The leader in promoting quality patient care by influencing standard setting and performance measurement in the specialty of pathology;
- The primary resource for information and education for pathologists, patients, and the public on the practice and science of pathology; and
- The most influential advocate for pathologists, patients, and the public on issues related to pathology.
The accreditation programs examine preanalytical, analytical, and postanalytical 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. Laboratories that meet accreditation requirements distinguish themselves as quality laboratories.

Accreditation Hierarchy

The Council on Accreditation (CoA) sets the strategic direction for the CAP’s laboratory accreditation programs consistent with the College’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 to advance the CAP accreditation programs to be the premier programs for the inspection and accreditation of medical laboratories; to administer the programs through the principles of peer review and education toward the goal of laboratory improvement in order that quality laboratory services are provided to patients and clients; to ensure that the programs continue to meet the scientific, service, and regulatory needs of participants; and to enhance the recognition of the pathologist as a physician in clinical decision making and consultation through the role of laboratory director.

The CLA oversees and coordinates the activities of the five CLA committees in the development, maintenance, and implementation of (i) accreditation checklists and standards, (ii) inspection processes, (iii) interinspection assessment tools, (iv) complaint investigations, and (v) program education; the CLA also ensures that committee priorities and activities are aligned with the overall goals, strategies, and tactics supporting the CAP 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 is another arm of the CoA responsible for ensuring objectivity and consistency in CAP accreditation decision making by centralizing the decision-making criteria and processes. The Accreditation Committee is responsible for all accreditation decisions on these programs based on the recommendations from the reviewing commissioners, technical specialists and other LAP committees as appropriate. In particular, the Accreditation Committee makes investigation and accreditation decisions in those more challenging and immediate jeopardy cases that may require a nonroutine inspection, suspension, probation, or accreditation status decision.

Commissioners

Many of the members of the CLA and LAP Committees also serve as regional commissioners. Each regional commissioner is 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 the 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.
Deputy, 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.

Inspectors and CAP Staff

The inspectors who conduct the on-site laboratory inspections are the lifeblood of the program. 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 laboratory accreditation 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 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 requirements set out in the Standards. The inspector collects information and records it on the ISR, and this information is the basis for the regional commissioner’s accreditation recommendation. In addition to verifying that regulatory requirements are being met, the inspection entails sharing information and ideas between the members of the inspection team and staff of the laboratory being inspected. This sharing of information results in ideas for laboratory improvement for all concerned, and the inspection team members often take a new idea or process back to their own laboratory.

Communication of Changes to the CAP Accreditation Programs

Changes in accreditation program policies and procedures are communicated to participants through eAlert communications and articles in CAP TODAY.

Standards for CAP Accreditation Programs

The Standards constitute the core principles of the College of American Pathologists’ 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 College accredits laboratories that conform to the Standards. Each of the four accreditation programs has its own Standards for Laboratory Accreditation. The CAP Board of Governors approves these standards, which have evolved through years of study and continuous review by the Commission on Laboratory Accreditation. 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, instrumentation; furnishings; communication and data processing systems; reagents and other supplies; ventilation; piped gases and water; public utilities; storage and waste disposal; and protection from hazardous conditions of patients, laboratory personnel and visitors.

Standard III encompasses quality management. This includes discussions of test system validations, quality control of pre analytic, 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 inspection 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 indicated by a declarative statement. The checklists also serve as instruments to guide the conduct of the inspection. The checklists are revised periodically and include approximately 3,000 requirements. Similar checklist requirements may appear in multiple discipline-specific checklists.

The checklists are organized by specific laboratory disciplines and/or important management operations as follows:

- Laboratory General
- All Common
- Anatomic Pathology
- Chemistry and Toxicology
- Clinical Biochemical Genetics
- Cytogenetics
- Cytopathology
- Flow Cytometry
- Hematology and Coagulation
- Histocompatibility
- Immunology
- Limited Service Laboratory
- Microbiology
- Molecular Pathology
• Point-of-Care Testing
• Team Leader Assessment of Director & Quality
• Transfusion Medicine
• Urinalysis
• Forensic Drug Testing
• Reproductive Laboratory
• Biorepository

Checklists are provided to accreditation program participants upon completion of the application/reapplication and again at accreditation midcycle during the self-inspection year.

To receive the checklists:
• Call 800-323-4040 or 847-832-7000 for a copy on CD.
• Download a master or custom electronic copy from the CAP website at cap.org by opting in to the CAP e-LAB Solutions™ page.

A laboratory will be inspected using the checklist version sent to it at the time of application/reapplication completion, even though a new version may have been released into the field since that time. The inspection team is sent, and must utilize, the same version that was sent to the laboratory. **It is likely that the checklist version sent for use in the self-inspection is different from the version used for the previous or next onsite inspection.**

**Determining Checklist Changes:**

A listing of new, revised, and deleted requirement numbers follows the table of contents of each checklist. A new, revised, or deleted requirement number will remain on the list for 18 months.

A “NEW” flag and the date of the edition in which the requirement first appeared indicate new checklist requirements. Significantly revised requirements are marked with a “REVISED” flag and the date of the edition in which the revision first occurred. Checklist summaries included in custom checklists will only reflect changes related to the laboratory’s own test menu.

As the checklists are revised, each will exist in three versions at the CAP website cap.org by opting in to the CAP e-LAB Solutions page:
• CAP current
• Onsite inspection
• Self-inspection

Each version may be accessed as one of three different types:
1. Master – contains all the requirements in the specified checklist
2. Custom – customized to the laboratory’s activity menu
3. Changes only – contains ONLY what has been changed, added, or deleted

Checklists may be downloaded in three different electronic formats:
1. PDF
2. Word/XML
3. Excel – provides a useful tool for cross-referencing a laboratory’s own policies and procedures with checklist requirements

These versions will remain at the website until they are no longer used in the field.

To hear the most recent “Checklists Update” audioconference, visit the CAP’s website at cap.org; select the Accreditation and Laboratory Improvement tab; under CAP Accreditation and Inspection Information, choose Preparing to Inspect/Training; and look under Inspector Resources to find the Virtual Library of Past Audioconferences. This is an annual topic.

Phase 0, Phase I, and Phase II Deficiencies

Each checklist requirement bears a designation of Phase 0, Phase I, or Phase II. A Phase 0 item may be included in the checklists for administrative purposes. It is not a requirement and does not require a formal response. Deficiencies to Phase I requirements compromise the quality of the services without endangering the health and safety of patients, clients, or personnel. If a laboratory is cited with a Phase I deficiency, correction and a written response to the CAP are required, but supportive documentation of deficiency correction is not required.

Deficiencies to Phase II requirements may have a serious impact on the quality of services or may endanger the health and safety of patients, clients, or personnel. All Phase II deficiencies must be corrected before the Accreditation Committee grants accreditation. Correction requires that the laboratory provide to the CAP both a plan of action and supporting documentation that the plan has been implemented.

Checklist Components

To anticipate and prepare for upcoming changes to checklist requirements, the CAP encourages laboratories to download and review the most recent edition of each checklist. These are available by opting in to e-LAB Solutions via the CAP website at cap.org. The website checklist format not only includes checklist requirements and notes, but it also includes references that may be helpful to the laboratory in determining corrective action. Three new components are also included in the website checklist:

1. **Subject Header** is a word or group of words found on the same line as the requirement number that provide a summary or key to the content of the requirement.

2. **Evidence of Compliance** is information targeted directly to the laboratory. This component suggests ways to document compliance with the requirement. Other types of documentation may be acceptable. Evidence of compliance will reference policies, procedures, records, reports, etc. specific to the checklist requirement.

3. **R-O-A-D** (Read, Observe, Ask, Discover) is provided as an inspection tool at the group level of the checklist requirements. This information enables the inspector to assess compliance by focusing on a group of related requirements rather than assessing each requirement individually.

Information in the **NOTE** is integral to the requirement and must be complied with just as much as the checklist requirement itself.
COMMISSION PHILOSOPHIES

Peer Review

**Purpose:** 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 postinspection process. Refer to the section “Post-inspection Phase: Challenging a Deficiency” in this manual. (See page 107.)

Thoroughness

The CAP inspection process is approved by the Centers for Medicare and Medicaid Services (CMS) and must meet all regulatory requirements. Additionally, participating laboratories expect a thorough, detailed, and fair inspection. All pertinent items in the customized checklist should 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 xx 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 may contact the CAP’S laboratory accreditation technical staff by telephone during the inspection (800-323-4040 ext 6065) and should participate in any such calls initiated by the laboratory personnel. 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 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 contacts 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 should not solicit in any way 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 medical director is there 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

Any US-sited laboratory inspected by the CAP or by any other accrediting agency is required to have an agreement between itself and the accrediting agency protecting the privacy and security of patient health information. The College has developed for its accredited laboratories a standardized model agreement to be used to meet the Health Insurance Portability and
Accountability Act of 1996 (HIPAA), the privacy and security regulations promulgated there under, and Subtitle D of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). The model business associate agreement is posted at the CAP website.

The CAP further protects the CAP-accredited laboratory by informing its inspectors and any other personnel who may have access to protected health information of their obligation to keep this information confidential and to use such information only within the context of the inspection itself. The Inspector’s Summation Report includes an agreement from each inspector indicating that he or she will treat protected health information confidentially. In additional, 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 College. Inspectors approached in this regard by a laboratory, patient, or an attorney regarding inspection activities should contact the College immediately to invoke this provision. Inspectors may not discuss any inspection findings with anyone outside the inspected laboratory or the College.

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 the inspector inspects. An inspector must not solicit or accept gifts of any type, including personal gifts, products, services, or entertainment. Neither shall an inspector discuss, solicit, accept, or have an employment or consulting arrangement, referral of business, or other business opportunity with the laboratory that the inspector inspects.

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.

For all routine and initial inspections, as well as inspections of international laboratories and laboratories participating in the CAP Reproductive Laboratory Accreditation Program (RLAP), Forensic Drug Testing (FDT) Accreditation Program, or Biorepository Accreditation Program, the inspected laboratory may discuss the specifics of a perceived conflict of interest with CAP staff or the state and/or regional commissioner prior to the inspection. Any perceived/new conflicts of interest should be reported as soon as possible to CAP headquarters. To report a perceived/new conflict of interest with another institution, a laboratory must complete and return
the conflict of interest form that is found in the self-evaluation packet or contact the CAP at 800-323-4040. The laboratory must provide the name and location of any perceived conflict of interest on the conflict of interest form. 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.
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 or the Analyte/Procedure Index of the CAP Surveys or EXCEL catalogs.
- For tests that do not require enrollment in a CAP-accepted PT program, the laboratory must perform an alternative 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 assessment procedures are listed in the Accreditation Checklists and on page 40 of this manual (Inspecting the Laboratory Sections).

Application

A laboratory seeking accreditation by the CAP must submit an application request form along with a nonrefundable application fee. Once the request has been processed, the CAP will send application materials to the laboratory. The application materials are organized into a binder in four sections. The first section will have all the necessary forms for the formal application. The other parts of the binder include the Standards for Laboratory Accreditation and this manual. Master version inspection checklists are located on the enclosed CD-ROM, and are also available on the CAP website cap.org by opting in through the CAP’s e-LAB Solutions. A letter confirming that application materials have been sent to the laboratory is included in the binder and may be used as documentation that the laboratory has initiated the CAP accreditation process.

A new applicant to the accreditation program has up to six months to complete and return the application materials. The laboratory may either return a paper copy of the application or may submit an electronic version at cap.org through e-LAB Solutions. The application materials for the Biorepository Program are not yet available through e-LAB Solutions.

The CAP must individually accredit each laboratory within an institution that operates under a separate CLIA license. Two laboratories under separate CLIA numbers at the same address must have separate CAP numbers, and likewise must enroll in separate PT products and not share samples. 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.
Application Forms and Supplemental Materials

Before the first on-site inspection, each laboratory must complete the following application materials preferably online through e-LAB Solutions (see below for BAP application material):

- Application forms that address general laboratory information, including demographics, personnel, contacts, licensure and certification, affiliated laboratories (laboratories that qualify to be inspected together), and terms of accreditation.
- "New Laboratory Section" form must be completed for each section including: section name, responsible personnel, number of technical full-time employees (FTEs), and an estimated annual test volume. (See Appendix B: Guidance in Determining Test Volume.). A section address must be provided if different from the address of the physical location 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. If submitting a paper application, applicable discipline specific pages from the Master Activity Menu should be returned with appropriate test activities circled.

Note: A Laboratory General section is automatically created for all laboratories. Please refer to Appendix E: Laboratory General Activity Menu Reference Guide to select appropriate Laboratory General codes for your laboratory. If specific Laboratory General codes are not returned with the application, the CAP will automatically add all codes in Appendix E.

- Supplemental materials, as follows:
  - Test catalog (a list of all patient testing performed by laboratory)
  - Most recent previous accreditation inspector report (required from laboratories previously accredited by another agency)
  - Laboratory Director Questionnaire (Attachment A)
  - Organizational chart, including names and titles
  - Medical director's curriculum vitae (please remove the Social Security number)
  - Current CLIA certificate (or CLIP certificate for Department of Defense laboratories) and state licensure certificate, if applicable
  - Instrumentation List
  - Personnel Evaluation Roster (signed by director)
  - Personnel Forms for director, staff pathologists, administrative manager, accreditation contact, quality assurance contact, proficiency testing contact, section director and section supervisors.
  - Travel and Lodging Form

The Commission on Laboratory Accreditation expects that the laboratory will review all applicable checklist requirements in order to ensure that it meets the Standards for Laboratory Accreditation by the date the laboratory returns the application materials to the CAP.

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 quality control procedure with the specific control materials used for each test (content, concentration).

• 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 quantitation values
  • 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

• Application forms that address general biorepository information, including demographics, personnel, contacts, and affiliated biorepositories.

• Laboratory Section pages for each section of the laboratory. 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. If submitting a paper application, these pages may be copied if testing is done in more than one section.

• Supplemental materials, as follows: the Director’s curriculum vitae (please remove the Social Security number); an organizational chart, including both names and titles; floor plan: and travel and lodging information forms.

The Commission on Laboratory Accreditation expects that the laboratory will review all applicable checklist requirements in order to ensure that it meets the Standards for Laboratory Accreditation by the date the laboratory returns the application materials to the CAP.

Laboratory Disciplines

All disciplines (See Appendix H: Glossary of Terms) practiced by the laboratory must be listed in the application, and all disciplines will be inspected. The College does not accredit portions of laboratories.

CAP disciplines/subdisciplines and CMS specialties/subspecialties (when appropriate) will be determined by the selection of activities from the Master Activity Menu. The accreditation letter lists only those 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 College either
electronically via e-LAB Solutions or in writing; in some cases, additional inspections for added disciplines may be required. (See the Nonroutine Inspections section of this manual on page 118.)

Activity Menu

The laboratory provides information about its scope of testing and lists all reportable assays in its activity menu. The information provided is critical, as it is used to customize checklists, to determine disciplines for which accreditation is granted, to verify proficiency testing enrollment, and to determine the laboratory’s annual fee. Accuracy in completing this document is essential.

Reapplication Forms

For previously accredited laboratories, the CAP provides reapplication forms 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. The following supplemental information must be provided at the time of reapplication: organizational chart, director CV, instrument list, CLIA certificate (CLIP certificate for DOD laboratories), personnel evaluation roster, personnel forms, and travel and lodging information.

AABB Coordinated Inspection

Laboratories wanting a CAP/AABB coordinated inspection of their transfusion medicine service must indicate that request on the LAP application/reapplication form. 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. Please refer to the “Preparing for the Inspection” and “AABB Coordinated Inspection” sections on page 30 in this manual.

Accreditation Checklists

• CAP staff determines checklist usage from the activity menu completed for each laboratory section. Depending on the organization of the laboratory, more than one checklist may apply to any one laboratory section. Supervisors should prepare for inspection using the appropriate discipline-specific checklist(s). Similarly, the laboratory director should review the Team Leader Assessment of Director & Quality Checklist, which evaluates the qualifications of the laboratory director and the director’s ability to implement the Standards for Laboratory Accreditation Program, as well as the overall effectiveness of the laboratory’s quality management system.
  Note: In the biorepository accreditation program, each section defined by the biorepository will be assigned a separate biorepository checklist. The Team Leader Assessment of Director and Quality Checklist does not apply.
• The checklists used for inspection are customized based on the laboratory’s activity menu. Subdiscipline sections and other significant groups of requirements not pertinent to the testing performed in the laboratory are not included. Customized checklists greatly reduce the number of nonapplicable checklist requirements.
• After processing the application/reapplication, the CAP sends the customized checklists to the laboratory and the inspection team. This checklist version is the one with which the
laboratory will be inspected, regardless of whether another version is released before the time of inspection. Custom checklists can also be viewed online and downloaded in PDF, Word, or Excel format by accessing CAP e-LAB Solutions. The downloaded checklists may be copied, if needed.

- Duplicate discipline-specific checklists are required in instances where there is more than one laboratory section performing testing within the same discipline and under the operation of different supervisors (e.g., a separate blood gas laboratory with a different director or technical supervisor). The CAP will provide the appropriate quantity of each checklist to the inspector.

- **Checklists should not be returned to the CAP headquarters.** See Appendix A for a detailed explanation of checklist usage.

**Returning the Application**

Return completed application forms and supplementary material to:

CAP ACCREDITATION PROGRAMS  
COLLEGE OF AMERICAN PATHOLOGISTS  
325 WAUKEGAN ROAD  
NORTHFIELD, IL 60093-2750
PREPARING FOR THE INSPECTION

Training the Inspection Team Leader and Team Members

CAP requirements for inspector qualifications to include successful completion of 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 within two years prior to conducting an inspection. Team leaders must ensure that their team members have fulfilled the training requirement.

Specially designed training options emphasize the knowledge and skills required by team leaders and team members. Both team leaders and team members should use the initial training option for their first encounter with inspection training. Thereafter, both may use the update training option for additional sessions. Effective 2013, there will be one team leader and one team member course; participants will select the content that is most relevant to their needs. Each option offers CME/CE credit for participants and is updated annually.

To fulfill the training requirement, in addition to completing the appropriate course work, participants must successfully pass the post-test. Passing scores are 72% (18 out of 25 questions) for team leaders and 70% (14 out of 20 questions) for team members. Participants will have a total of three opportunities to pass the post-test. Pathologists who pass the post-test may apply their earned credits to the American Board of Pathology (ABP) Self-Assessment Module (SAM) requirement.

To enroll in any of the training options for team leader or team members, access the CAP website at cap.org, click on the Accreditation and Laboratory Improvement tab and select Preparing to Inspect.
Optional Educational Activities

*LAP Audioconferences/Webinar Series:* These LAP presentations assist laboratory professionals in remaining current with accreditation requirements and in efficiently and effectively managing everyday operations. The entire laboratory staff can learn about key topics that are of interest to both inspectors and laboratory personnel preparing to be inspected. Each site must identify a site coordinator and have access to a speaker phone and—for webinars—Internet access. There is no limit to the number of participants at any one registration site. Participants may claim CME/CE credit for each session attended.

To register for the LAP audioconference/webinars, access the CAP website at [cap.org](http://cap.org), click on the Accreditation and Laboratory Improvement tab, and then select Continuous Compliance Series. NOTE: LAP audioconferences/webinars do not fulfill the training requirement for team leaders or team members.

*Previously Broadcasted Audioconferences:* Previously broadcasted audioconferences, including both audio files and handouts, are available at the CAP website to purchase at a reduced fee.

Topics range from inspection basics to how to inspect the various laboratory sections, and all are available 24 hours a day for downloading. NOTE: Starting in 2013, audioconferences will offer CE credit but do not fulfill the team leader or team member training requirement.

A sample of available topics includes:

**General Topics**
- Achieving Compliance With Limited Resources
- Avoiding the Most Common Deficiencies
- CAP Personnel Qualifications and Competency Requirements
- Checklists Update
- Complying With the Team Leader Checklist
- Continual Inspection Readiness
- Crucial Compliance Communications
- Document Control Management
- Getting the Most Out of Your Proficiency Testing
- How to Validate a New Test
- Laboratory Computer Systems
- Laboratory Developed Tests
- Patient Safety and the Laboratory
- Performing Effective Self-Inspections
- Personnel Issues in the Clinical Laboratory
- Quality Management from the Top Down
- Quality Management Plan
- Safety for Laboratory Workers
Discipline-specific Topics

• Anatomic Pathology for Histotech
• Blood Gas Analysis
• Coagulation
• Cytopathology
• Molecular Pathology Laboratory
• Most Common POCT Deficiencies
• Teat Validation: Anatomic Pathology

Inspection Team Leader Assignment

The inspector assignment process has been improved to ensure that the appropriate team carries out each inspection, and that the inspection team has the opportunity to inspect a laboratory most like its own. The automated process matches team leaders to a single prospective assignment after screening against multiple criteria, including completion of training, known conflicts of interest, geographic distance, and size and complexity of the respective laboratory. A laboratory is asked to perform a reciprocal inspection approximately every 18–24 months. The CAP’s state commissioners will screen assignments, and the notification of assignment will arrive by mail. Assignments can be made up to 15 months prior to the anniversary date of the laboratory being inspected.

Refer to Appendix C for Unannounced Inspection Tips for the Laboratory and the Inspectors. (See page 124.)

Team Leader Qualifications

Team leaders should be:

• A peer of the laboratory/biorepository director with similar status, type of practice, and hospital or laboratory or 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 (for instance, 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. A pathologist board certified in anatomic pathology must inspect, or supervise the inspection of the anatomic pathology sections if performed by qualified histotechnologists or cytotechnologists, (with the exception of a small laboratory doing only specimen accessioning and/or frozen sections). In this situation, a CAP staff inspector may inspect the laboratory. A CAP staff inspector is a medical technologist and performs inspections for certain limited service laboratories. The Team Leader for a biorepository must have the qualifications to be a director of a biorepository. Refer to the Team Leader Planner. The staff inspector assignment specialist at the CAP headquarters makes these assignments. Refer to “Staff-inspected Laboratories.” (See page 96.)
Inspector’s Inspection Packet

The Inspector’s Inspection Packet is sent to the inspection team leader from the CAP headquarters and includes the following materials:

• Standards for Laboratory Accreditation
• Laboratory Accreditation Manual
• Team leader inspection materials
  1. Team Leader Inspection Planner (see Appendix J)
  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. Inspector list by specialty
  6. Team Leader Evaluation form
  7. Claim for Inspection Reimbursement form
  8. Travel and Lodging Information from
  9. List(s) of qualified specialty inspectors, (applicable to cytogenetics, flow cytometry, histocompatibility, and molecular pathology only)
  10. CD-ROM containing checklists
  11. Name tags for the team (every team member should wear a nametag while in the host facility)
  12. Prepaid mailer envelope to return the packet to the CAP within 24 hours after the inspection is complete. These mailers can only be used within the 48 contiguous states.

• Accreditation unit (AU) materials, including:
  1. Laboratory Synopsis Report
  2. Letter for laboratory director announcing inspection, if applicable
  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 curriculum vitae
  11. Inspector’s Summation Report from previous on-site inspection
  12. Lab-specific activity menu (list of tests and testing modalities)

• Section unit (SU) materials, including
  1. Laboratory Section Synopsis Report
  2. Team Member Inspection Planner (See Appendix K)
  3. Instrumentation list
  4. Proficiency Testing Performance Report
  5. Team Member Evaluation form
• Checklist section
  1. Previous Inspector’s Summation Report (ISR)
  2. Activity menu
  3. ISR Deficiency form
  4. ISR Recommendation form
  5. Customized checklist (based on the laboratory’s activity menu for the laboratory section where the checklist should be used)

Assembling the Inspection Team

The team leader assembles a trained inspection team appropriate for the size and scope of the laboratory. Selecting an appropriately sized team affects the efficiency of the inspection, the degree to which routine laboratory activities are interrupted during the inspection, and the cost of administering the accreditation program.

Upon receipt of the Inspector’s Inspection Packet, the team leader should immediately review the materials to determine the number of inspectors, as well as whether specific expertise is needed. The Inspector’s Inspection Packet includes information regarding the size of the previous inspection team and recommends the number of inspector days needed to perform the inspection, based upon the disciplines and test volumes declared by the laboratory. Particular expertise is invaluable if the volume of testing is very high or if the level of testing is unusually sophisticated. When planning for the inspection of large or multisite laboratories, give strong consideration to the efficiency of spending more than one day on site with a smaller team, rather than taking a team large enough to complete the inspection in one day. Particularly with multisite laboratories, each section supervisor may be responsible for more than one site, and may therefore not be available at more than one site during a one-day inspection.

Generally, one inspector is needed for the Laboratory General inspection, and one for each of the following checklist combinations: Hematology and Urinalysis; Chemistry and Toxicology (when chemistry, special chemistry, and toxicology analyses are all performed); Microbiology and Immunology; and Anatomic Pathology and Cytopathology. If the laboratory does not have a donor center, the Transfusion Medicine Checklist can be combined with another checklist, such as Immunology or Point-of-Care Testing. Each section unit also receives an All Common Checklist. The inspector assigned to each section is also responsible for the All Common Checklist in that section unit. Adjustments to the number of inspectors should be made based upon the experience of the inspectors and the extent of testing in the laboratory.

For a large, full-service laboratory, such as a university hospital laboratory, more than one inspector may be required to inspect the Laboratory General Checklist. Inspectors assigned to other checklists may be able to assist the laboratory general inspector by inspecting the computer, water quality, glassware washing, and safety requirements. If the laboratory has donor and transfusion activities, an additional transfusion medicine inspector may be needed to complete the inspection in one day. If the laboratory offers microbiology services in all subdisciplines (bacteriology, mycobacteriology, mycology, parasitology, and virology), two inspectors may be required to complete the inspection in one day.

Fewer inspectors will be required for a laboratory with a very limited test menu. Often only a single inspector is required to inspect testing when the Limited Services Laboratory Checklist is used.
If it is considered necessary to increase the size of the team beyond the CAP recommended number provided in the inspector packet, approval is required from LAP management and the assigning commissioner. The Inspection Assignment Worksheet by Laboratory form, included in the packet, must be completed with an explanation of the need for additional inspectors and faxed to CAP headquarters at 847-832-8171. CAP headquarters will notify the team leader whether or not additional inspectors have been approved within two business days. Additional inspectors may not be reimbursed without prior approval.

The team leader’s three major responsibilities are: 1) the overall supervision and time management of the team throughout the inspection process, 2) the completion of the Team Leader Assessment of Director & Quality Check list form, and 3) the administration of the interviews that are a part of that process. Because of this, the CAP strongly encourages the team leader to be judicious in taking on other inspection responsibilities and, at most, inspecting with only one other checklist.

Inspection Team Members:
• Must have expertise in their assigned inspection area. This enhances the peer review aspect of the inspection experience, as well as the quality of the education received.
• Must be chosen from the list of specialty inspectors provided in the inspection packet if the laboratory being inspected requires a cytogenetics, flow cytometry, histocompatibility, or molecular pathology inspector.
• May include medical technologists, cytotechnologists, histotechnologists, clinical scientists, laboratory/biorepository supervisors, laboratory/biorepository managers, pathology residents and fellows, and pathologists.
• Can be located using the CAP inspector database. Lists of qualified inspectors may be obtained from the CAP by calling 800-323-4040 ext. 7380 or 847-832-7380.
• Cannot inspect a laboratory or facility for which he or she has provided or is likely to provide consultative services.
• Must not be engaged in close personal, family, business, or professional relationships with any personnel in a laboratory or biorepository that the inspector inspects.
• Are trained in the inspection process. (See Preparing for the Inspection on 23.)
• Should review the information supplied by the team leader from the inspector’s packet, including the Laboratory Accreditation Manual, activity menu, instrumentation and equipment lists, Previous Deficiency Report, PT Performance < 100% Report (if applicable) test volumes, section personnel, Team Member Inspection Planner information (Appendix K), and applicable checklists several weeks before the inspection in order to be prepared to perform a thorough and efficient inspection. Each inspector must also be familiar with the safety and test method validation requirements in the Laboratory General and All Common Checklists.

Arranging the Inspection Date

This information applies only to announced inspections that will occur for laboratories seeking initial accreditation and for RLAP, FDT, BAP and international laboratories.
After accepting the assignment for these laboratories, the inspection team leader should arrange the inspection date. (See the Team Leader Inspection Planner information [Appendix J] for details). 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 within the 90 calendar days before the laboratory’s accreditation anniversary date.** A mutually acceptable date is preferable; however, the inspection is scheduled at the convenience of the inspector.
- Notify the CAP Accreditation Programs at CAP headquarters of the inspection date and the number of inspectors. Contact the inspection assignment specialist by telephone at 800-323-4040 ext. 6061 or 847-832-7000, by fax to 847-832-8171, by mail, or by email to 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, quality control and maintenance records, and a sampling of completed case records [as applicable]). (See an example of the template letter in Appendix D.)
- **Unannounced inspections:** Consider preparing an inspection schedule that can be handed to the laboratory director at the beginning of the day. At a minimum, this would consist of a list of inspectors and their section/checklist responsibilities.

## 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. **If air travel and/or more than 10 total hotel nights are required, arrangements must be made through the CAP Travel Desk.** The agents can be reached at 800-323-4040 ext. 7800 or 847-832-7800, from 8:00 AM–5:00 PM Central Time. Alternatively, you may fax to 847-832-8800 or send an email to captraveldesk@cap.org 24 hours a day.

The five-digit Inspection Instance (II) identification number of the laboratory to be inspected must be given to the agent when booking travel. Provide the inspector names, gender, and birthdates **exactly** as they appear on the photo identification that they will use for traveling. The College encourages booking two months prior to travel in order to obtain favorable rates. When planning for the inspection, follow the recommended number of inspector days. If the team leader believes additional inspector days will be required to conduct a quality inspection, the Inspection Assignment Worksheet by Laboratory form (located in the inspector packet) must be completed and returned to CAP headquarters for approval. Travel arrangements cannot be made until the additional inspector days have been approved. Direct questions to 800-323-4040 ext. 6061. If a team member needs to change his/her ticketing for the return trip, contact the CAP Travel Desk agents as soon as possible.

The CAP Travel Desk agents can also arrange hotel accommodations and rental cars, if applicable. All inspectors from Department of Defense (DOD), Indian Health Services (IHS), and Department of Veteran’s Affairs (VA) must make their travel arrangements through the CAP.
Travel Desk. The CAP Travel Desk can negotiate a master account to cover the room rates and tax for inspectors. Inside the US, decline insurance for rental cars. Outside the US, the inspector should purchase the rental car insurance. Prior to the inspection, the inspector’s personal auto insurer should be contacted to advise them that he/she will be driving outside of the US. (Refer to Appendix F for additional information concerning travel planning for inspections at facilities with multiple sites.)

Requests for Inspection Delays

CLA 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 state or regional commissioner for resolution.

AABB Coordinated Inspection

- Once notification is received from AABB that an AABB inspector has been assigned, the CAP will provide the name and telephone number of the CAP team leader to the AABB inspector via a letter. The letter includes detailed instructions and information to help ensure that the inspection goes smoothly.
- When the laboratory’s reapplication is complete, the CAP will mail an Inspector Inspection Packet to the AABB inspector containing the Transfusion Medicine and Laboratory General Checklists, an Inspector’s Summation Report (ISR) form, instructions, and a return envelope.
- The AABB inspector should contact the CAP team leader to see if concurrent unannounced inspections are possible. If possible, the AABB inspector will join the team on the inspection day.
- If the AABB inspection cannot be concurrent with the CAP inspection, the AABB inspector may perform a separate unannounced inspection of the blood bank. The inspection date should occur before the CAP anniversary date.
- In either case, concurrent or separate inspections, the AABB inspector should notify the CAP of the inspection date.
- Following the AABB inspection, the completed CAP Transfusion Medicine ISR must be returned to the CAP in the envelope provided.

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

Each organization (the CAP and AABB) makes separate accreditation decisions, and one organization’s decision does not affect the other.
CONDUCTING THE INSPECTION: GENERAL PRINCIPLES AND MEETINGS

General Principles: How to Inspect

Preparing to Inspect: The inspector must be thoroughly familiar with the checklist(s) that will be used during the inspection. Prior to the inspection, each inspector should review the assigned discipline-specific checklist(s), the All Common Checklist and the Laboratory General Checklist. The R-O-A-D (Read, Observe, Ask, Discover) component, as well as the Evidence of Compliance (EOC) component, is found in each checklist. Inspectors are encouraged to utilize these tools to streamline the inspection process. Requirements in the Laboratory General Checklist apply to every laboratory section. During the inspection of each section, each inspector should verify compliance for proficiency testing, safety, and the physical environment. If the intent of any checklist requirement is not clear, CAP staff can offer further explanation or interpretation before the inspection through the accreditation email site (accred@cap.org), or before or during the inspection at 800-323-4040 ext. 6065.

Review of the Activity Menu: The laboratory’s activity menu and instrumentation lists help the inspector understand the type and scope of testing the laboratory is performing. For each section, the activity menu is packaged with the checklist(s) to be used. The inspection checklists are customized based on the laboratory’s activity menu. If an inspector discovers testing being performed that is not included in the activity menu, the inspector should contact CAP staff so that appropriate action can be taken (for instance, faxing a required checklist section to the inspection site. (See Appendix E.)

How to Begin the Inspection: One hour prior to arriving, the team leader contacts the laboratory using the one-hour security notice phone number provided in the inspector packet cover letter. Each inspector should bring a photo ID. For unannounced inspections, arrive 30–60 minutes sooner than for an announced inspection. This allows enough time to get through security, if applicable, and gives the lab sufficient time to locate key personnel and make other arrangements. The inspection team leader will present the letter supplied by the CAP verifying that the inspection is to occur on that day under the direction of the team leader. BAP, RLAP, and FDT inspections are announced. The team leader and the facility director will determine the date and time the inspection takes place.

After introductions and a brief overview of the day’s schedule, most inspections begin with a brief tour of the laboratory. Many inspectors find it helpful to “follow a specimen” through the laboratory, which addresses the preanalytic, analytic, and postanalytic aspects of laboratory testing. This process is generally followed by review of the laboratory’s documentation.

Using the R-O-A-D technique: The on-site evaluation of a laboratory’s performance should use these techniques: Read/review documentation; Observe procedures/technique; Ask probing questions; Discover the path of a specimen—follow the R·O·A·D. The inspection should allow adequate time for all components.

R·O·A·D icons are placed at the group level within the checklists. The icons may also appear in the margin next to the appropriate checklist requirement when there are specific instructions to the inspector.

Example:
Read/review documents 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 the past two years’ documentation for transfusion reaction workups.

Observe laboratory practices by looking at what the laboratory personnel are actually doing.
For example:
• Observe a phlebotomy from receipt of requisition to delivery of the specimen to the laboratory.
• Note if practice deviates from the documented policies/procedures.

Ask open-ended, probing questions as starting points. This will allow you to:
• Obtain large amounts of information
• Clarify your understanding of the documentation and observations
• Assess the laboratory’s understanding of the requirements

Asking the laboratory staff open-ended questions eliminates the need to focus on each checklist requirement separately, since the dialogue with your laboratory counterpart may address multiple requirements.

Asking open-ended questions that start with phrases such as “Show me how …” or “Tell me about …” or “What would you do if …?” avoids staged answers. For example, “Could you show me the specimen transport policy and describe how you ensure optimum specimen quality?” helps the inspector to determine how well the technical staff is trained, and whether or not they are adhering to the laboratory’s procedures and policies. This provides a feel for the general level of performance of the laboratory.

Follow-up questions may be used for clarification.

Asking laboratory staff questions that can be answered simply by review of a chart or other form of documentation should be avoided. For example, instead of asking, “Is there documentation of corrective action when control results exceed defined acceptable limits?” the inspector could ask, “What would you do if the SD or CV doubles one month?” A follow-up probing question could be; “What would you do if you could not identify an obvious cause for the change in SD or CV?”

Direct observation coupled with asking probing questions helps the inspector to ensure that:
• Outcomes for any problem areas (e.g., PT failures and issues/problems identified through the quality management process) have been adequately investigated and resolved
• Previously cited deficiencies have been corrected

Discover/follow a specimen from collection to reporting covers multiple checklist requirements such as:
Requirements related to 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: The inspector observes a laboratory’s activities and reports the findings. The inspector will (Read) look at all types of documentation, including procedure manuals, quality control and proficiency testing records, instrument maintenance records, and test method validation studies. As the inspector examines procedures and documentation, it is a good practice to make a note of questions to be asked (Ask) while observing the laboratory section and interacting with laboratory staff at the bench (Observe).

Evidence of Compliance (EOC) suggests ways to document compliance with checklist requirements. Other types of documentation may be acceptable. It provides specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc) that should be acceptable to the inspector.

Procedure manuals should be complete, current, available to staff, accurate, and descriptive of good laboratory practices; and the laboratory director or a documented designee should review them at least biennially. QC and PT records must be complete, be reviewed, and show evidence of troubleshooting and error resolution. PT must be performed for every test performed by the laboratory, regardless of test complexity. Records of validation testing must be available to the inspector regardless of when the laboratory implemented the test, and the records must be available for two years after the test or method is retired. For each nonwaived test, the laboratory must have data on the test's accuracy, precision, analytic sensitivity, interferences, and reportable range as applicable.

In addition to examining documentation, the inspector will observe laboratory practices to verify that actual practice matches the written policy or procedure. The inspector should ask probing questions of the laboratory staff, technical staff, and supervisors, and the inspector must spend a significant amount of time in the laboratory observing staff performing the testing.

Biorepository inspections will consist of requirements from the Laboratory General and Biorepository checklists. Inspectors review policies and procedures, the quality management plan, quality control, instrument maintenance and specimen processing methods. The inspector should conduct a thorough review of specimen handling processes, including storage, preservation, and disposition of specimens. Inspectors also should examine the biorepository’s information systems and informed consent and institutional review board practices. The inspection will also consist of a review of safe work practices, personnel records, physical facilities, and an assessment of the biorepository director.
**How Much to Look at:** Since it is not possible for the inspector to review every procedure, quality control record, or piece of analytic data, the inspector should consult the laboratory’s activity menu and selectively focus on areas of highest and lowest test volume, likely problem areas and test results with the highest impact on patient care. It is usually more instructive to review the records for 10 analytes or procedures comprehensively than to review the records for 50 tests superficially. If applicable, the inspector’s packet includes a PT Performance <100% Report that identifies, by analyte, all of the PT scores below 100% that occurred during any of the last six testing periods. Good habits of experienced inspectors include: correlation of any PT problems with QC and maintenance records from around the same time interval; thorough review of these representative records, with data selected from the beginning, middle, and end of the period since the last on-site inspection; comprehensive review of records in the preanalytic (order entry and specimen collection, processing and transport), analytic (procedures, QC, PT, instrument setup, and maintenance), and postanalytic (reports, reference ranges, and critical value notification) categories; and if problems are discovered (Discover), review of similar records for additional analytes. Discover is a technique used to further evaluate areas of concern. “Follow the specimen” and “teach me” are two examples of Discovery. Utilizing this technique will allow the inspector to examine preanalytic, analytic, and postanalytic processes while reviewing multiple requirements simultaneously.

**Using the deficiency report from the last inspection, the inspector must verify that all previous deficiencies have been corrected, paying particular attention to recurring deficiencies.**

**How to Obtain Information:** Courtesy and consideration are important. Laboratory personnel should be interviewed, not interrogated. Open-ended, probing questions that require more than a yes/no answer are preferred, such as “Could you explain how you track QC data?” or “What type of follow-up do you perform when your PT results are evaluated as unacceptable?” Do not just reiterate the checklist requirement verbatim; rephrase the requirement, using language such as “Could you show me how you…” or “Explain the system you use for…” or “How do you document that…”?

The inspector should spend time in the laboratory observing the testing process and asking questions of bench technologists and supervisors, rather than spending the majority of time in a room reading documents. 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.

**When to Cite a Deficiency:** The laboratory practices must meet the intent of the checklist requirement, but the laboratory does not have to do things exactly as they are done in the inspector’s laboratory. There are many ways to accomplish the same objective. The inspector should cite a deficiency if there is no policy or procedure; if it is not being followed or documented as written; if there is no record of review or corrective action; or if the procedure is ineffective or a bad laboratory practice. In the situation where documentation or records are incomplete, the inspector must judge whether the degree of partial compliance is likely to have adversely affected patient care or worker safety. If so, a deficiency must be cited. If the checklist item applies but the laboratory does not address it in any way, the laboratory is not in compliance.
The inspector should not be afraid to cite a deficiency and should never give a recommendation instead of a deficiency if the laboratory is not in compliance. When an inspector gives a recommendation instead of a deficiency in a situation where the laboratory is clearly deficient, the CAP technical staff or the regional commissioner may convert the recommendation to a deficiency and ask the laboratory to respond to and correct the deficiency. The goal of the inspection is laboratory improvement.

**How to Cite a Deficiency:** Be specific. State the finding, not the checklist requirement! On the deficiency page of the ISR, write down the checklist item number followed by the exact nature of the deficiency. Clearly indicate the specific manner in which the laboratory is noncompliant, citing specific examples (ie, date, PT code number, instrument, etc), if possible. Write/print legibly.

**When to Give a Recommendation:** A recommendation is a suggestion for improvement; for instance, when a laboratory is in compliance, but it can improve its process. A recommendation may not always pertain to a specific checklist item, but could relate to the way the laboratory is doing something or keeping records. The laboratory is not obligated to respond to or implement a recommendation. A recommendation should not be given rather than a deficiency just to be “nice.” If a laboratory is not in compliance, it is deficient. A recommendation that should have been cited as a deficiency may be changed to a deficiency by CAP staff, and a deficiency response will be required from the laboratory.

**When Differing Interpretations of a Checklist Item Occur:** The inspector and the respective laboratory representative are encouraged to get together and call the College’s technical support line at 800-323-4040 ext. 6065 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. This can result in fewer improperly cited deficiencies and laboratory deficiency challenges post-inspection.
HOW TO INSPECT USING THE CHECKLIST(S)

Ensure Effective Document Control: The inspector should become familiar with the quality of the laboratory’s documentation by reviewing a representative sampling of that laboratory’s documents. This review may be in either electronic or paper form. Document review verifies that policies, procedures, and manuals are complete, current, available to staff, accurate, reviewed, and describe good laboratory practice. All policies, procedures, and processes covered in the CAP checklists must be documented. The current version should be available to staff and show appropriate review by the medical director. Make notes of any questions you may have or processes you would like to observe as you read the documentation to ensure that current practice matches the policies and procedures. Quality management (QM) forms and other records should have revision dates or version numbers that verify the current form(s) are in use.

The new checklist component, Evidence of Compliance (EOC), provides specific examples of acceptable documentation, such as:

- Written policy describing proper handling of PT specimens AND
- Instrument printout and/or work records AND
- Attestation pages from submitted PT result form reflecting rotation among testing personnel

These examples will help the inspector more accurately assess compliance. However, other types of documentation may also be acceptable.

Verify PT Problems Have Been Resolved: The PT Performance < 100% Report in the inspector’s packet identifies by analyte all of the PT scores below 100% during the previous six PT events. The last page of the report also indicates activities for which the laboratory has not participated, by year and event. These records should be thoroughly reviewed, selecting data from the beginning, middle, and end of the period since the last on-site inspection. Corrective action should have been documented, deemed appropriate, and received documented review.

Currently, the Biorepository Accreditation Program (BAP) does not have proficiency testing requirements.

Review Correction of Previous Deficiencies: The list of deficiencies in the inspector's packet from the previous on-site inspection should be reviewed to ensure that they have been appropriately addressed.

Evaluate Preanalytic and Postanalytic Issues: The inspector may choose a representative specimen and follow the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories. Examples of discovery opportunities are described throughout the checklist.

Evaluate Analytic Processes: Using the Checklist Activity Menu in the inspector’s packet, the inspector should assess whether the menu reflects the laboratory’s current testing. The inspector should choose two or three analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records, and method performance validations for the last two years, selecting timeframes at the beginning, midpoint, and end of this timeframe. Compare instrument print-
outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

THE CONTENTS OF THIS CHECKLIST APPLY TO ALL SECTIONS OF THE LABORATORY. INSPECTION OF A DISCIPLINE-SPECIFIC AREA (e.g., ANATOMIC PATHOLOGY) IS NOT LIMITED TO THE CONTENTS OF THE DISCIPLINE-SPECIFIC CHECKLIST, BUT IT INCLUDES ALL APPLICABLE PORTIONS OF THIS LABORATORY GENERAL CHECKLIST. PERSONNEL FROM ALL SECTIONS OF THE LABORATORY MUST BE FAMILIAR WITH THE CONTENTS.

Using the Team Leader Assessment of Director & Quality Checklist

The team leader or team member who is qualified and trained to be a team leader must complete the Team Leader Assessment of Director & Quality Checklist (TLC). This checklist evaluates the qualifications of the laboratory director and the effectiveness of the director in implementing the Standards for Laboratory Accreditation, including the laboratory’s QM plan. The TLC also includes requirements to evaluate the overall performance characteristics of the laboratory. This tool makes it possible for the team leader to more easily conduct a thorough assessment of the overall effectiveness of the laboratory’s quality management program and includes instructions on how to conduct interviews with the laboratory director, hospital administrator, and chief of the medical staff. It assists the team leader in evaluating aspects of the laboratory that are at the core of quality: the laboratory director’s responsibilities, the quality management plan, and the laboratory’s relations with the institutional medical staff and administration.

For biorepository accreditation 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 administration and researchers (users of the biorepository’s services) if available, but this is not required.

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 Team Leader Assessment of Director & Quality 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 discuss the circumstances in the Inspector’s Summation Report.

Meeting With the Laboratory Director

Purpose: To help determine if the laboratory director has sufficient responsibility and authority for operation of the laboratory. The inspector should allow a minimum of 15–20 minutes for the meeting. If the director is not present during the unannounced inspection, the inspector should conduct this interview by telephone. In addition, on-site conversation with technical staff, administration, and the CMO may be used to validate the director’s involvement in laboratory operations.
The interview is an opportunity to:
• Evaluate the director’s activities as listed in the Team Leader Assessment of Director & Quality Checklist and the Standards for Laboratory Accreditation
• Identify if the director has any goals for the inspection, such as problems that the inspection experience might serve to resolve (eg, space problems, staffing shortages)

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

For hospital-based laboratories, the inspector should meet with the hospital administrator/CEO. Allow approximately 15–20 minutes for the meeting. It is a good idea not to schedule the meeting early in the day, since the team leader should have a sense of the laboratory’s operations first. For independent laboratories, the inspector should meet with an executive from the laboratory organization.

**Purpose:** Extend the College’s appreciation for participating in the accreditation program and to record an evaluation of the laboratory from the administration’s viewpoint.

The interview is an opportunity to:
• Ascertain the administration’s perception of the laboratory service
• 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
• Identify any areas of conflict

Points to communicate during the interview are:
• The goals of the CAP’s laboratory accreditation programs: education, laboratory improvement, and the establishment of best practices in laboratory medicine based on input from national experts
• The role of proficiency testing in the program
• The responsibility of the laboratory director for the overall operation of the laboratory, per the requirements of the CAP’s laboratory accreditation programs and CLIA regulations

The interview should include a discussion of all laboratories being inspected (ie, special function and satellite laboratories). **The CAP prohibits discussion of the laboratory’s financial and/or contractual arrangements.**

When speaking with the hospital administrator, the team leader should ask if the laboratory service level is appropriate to the requirements of the institution. The team leader should ask how the pathologists participate in hospital-wide committees, how effective they are in working with the medical and administrative staffs, and if they meet the expectations of the administration.

The inspector may record information from this interview in Part A of the Inspector’s Summation Report.
Meeting With a Representative of the Medical Staff

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.

**Purpose:** Determine whether the laboratory director and the laboratory staff have established an effective working relationship with the medical staff and are effectively supporting patient care.

The interview is an opportunity to:
- Evaluate how effectively 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 the cooperation of medical staff and pathologists in problem resolution.
- Judge the medical community’s perception of the effectiveness of the laboratory director and other pathologists, and determine if the laboratory director has sufficient authority to fulfill the needs of the medical staff and patients.

When meeting with the chief or other active member of the medical staff, the team leader should inquire about the scope, quality, and timeliness of laboratory services. The team leader should ask the medical staff representative for input on pathologist participation in medical staff committees, participation in institutional quality management (performance improvement) and patient safety activities, and participation in teaching conferences. The discussion should include all laboratories being inspected, including special function and satellite laboratories.

The inspector may record information from this interview in Part A of the Inspector’s Summation Report.

Meeting With Direct Health Care Providers

The inspector should visit certain direct patient care areas during the course of the inspection. For example, if transfusion services are provided, observation of a transfusion should occur, or point-of-care testing should take the inspector to the patient bedside. If the inspector wishes to visit other direct patient care areas, the inspector should request this from the laboratory director on the day of the inspection.

**Purpose:** Determine how the medical, nursing, and clerical staff use the laboratory data and communications.

The visit should include:
- Observation of phlebotomy if performed by laboratory personnel
- Review of laboratory portions of patient charts for clarity of presentation
- Assessment, through interviews, of laboratory responsiveness to clinical needs
• Identification of concerns that can be relayed to the laboratory director

Meeting With Clients of Independent Laboratories

Meetings with clients during an inspection of an independent laboratory are not required.

Other Meetings

For hospital laboratory inspections, the inspector may find it useful to meet with the institutional quality assurance manager (sometimes called quality/risk management). This person may have insights into the laboratory’s input into safety and other issues that put the institution at risk.

Inspecting Additional Activities, Disciplines, and Laboratories

Additional Activities/Disciplines Not Reported at Application/Reapplication

If the inspector notes that testing not reported to the CAP is being performed that involves additional checklist requirements, the inspector should contact the CAP immediately to determine if inspection of that discipline should proceed. This pertains only to testing being performed under the same CLIA number of the laboratory that is being inspected. If there is someone on the inspection team with the expertise to inspect the area and if the CAP determines that the inspection of this testing may proceed, the CAP will fax a customized checklist to the inspector or the inspector may print the necessary additional checklist items from the CD that is included in the Inspector’s Inspection Packet. The inspector must verify that the laboratory is enrolled in the appropriate proficiency testing for these analytes/activities. Place a note regarding this additional discipline in the Inspector’s Comments section of Part A of the ISR, along with whether or not it was inspected.

Additional Laboratories Not Reported at Application/Reaplication

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 should not be inspected. The inspector should inform the director to submit a formal application to CAP headquarters. The CAP will schedule an inspection at a later date. Biorepositories not included in the application as part of the CAP number being inspected will not be inspected.
INSPECTING THE LABORATORY SECTIONS

Note: Checklists are frequently revised and requirements may change. When information in this manual is not consistent with the currently published checklists, the currently published checklists contain the most accurate and up-to-date accreditation requirements. During the inspection, the inspectors must use the paper checklists supplied in advance by the CAP.

Some general requirements are applicable to all laboratory disciplines, sections, or departments. Some of these requirements are found in each of the discipline-specific checklists, or in the All Common checklist, and some are in the Laboratory General Checklist. Requirements applicable to all sections of the laboratory are discussed in the next section. For additional requirements specific to each individual discipline, consult the discipline-specific section of this manual.

Requirements Applicable to All Laboratory Sections

Quality Management: The laboratory must have a documented quality management program that systematically ensures the monitoring and evaluation of the quality and appropriateness of its patient care services, resolution of identified problems, and implementation of the program throughout all laboratory sections by the director. In laboratories that are part of a larger institution (e.g., a hospital), the laboratory quality management program must be integrated with the institutional program.

The laboratory must have a procedure that encourages employees to communicate any concerns or complaints about the quality of patient testing and safety to proper authorities. This policy must indicate that no retaliation will occur because of expressed concerns or complaints. The investigation and analysis of employee complaints and suggestions, with corrective and/or preventive action as appropriate, should be a part of the laboratory quality management plan and specifically addressed in laboratory quality management records. During the on-site inspection, the inspector will review records of employee input and follow-up by laboratory management.

Quality Control (QC): The quality control checklist requirements are designed to determine whether QC procedures are clearly defined, whether the laboratory director uses the quality control program to evaluate performance, and whether corrective actions are taken when necessary. In most cases, for quantitative testing, two levels of quality control must be performed each day of testing. Qualitative testing requires that a positive and negative control be run each day patient testing is performed. Electronic and onboard internal QC is acceptable as part of a quality control plan. The laboratory must determine QC acceptable limits, and it must define and document corrective action.

Before patient results are reported, QC data must be judged acceptable. The laboratory director or designee must perform secondary review of QC data at least monthly. Beyond these specific requirements, a laboratory may optionally perform review more frequently at intervals that it determines appropriate. The laboratory must follow state requirements if these are more stringent than those of the CAP.
**Reagents:** Reagents must be properly labeled with the following elements: content and quantity, concentration or titer, storage requirements, date prepared or reconstituted, and expiration date. This includes secondary containers. These elements may be recorded in a log (paper or electronic), rather than on the containers themselves, provided that all containers are traceable to the appropriate data in the log. There is no requirement to indicate on the label the date received or placed in service.

The laboratory must use components of reagent kits only with other kits that are of the same lot number, unless otherwise specified by the manufacturer. New lots and shipments of reagent must be checked against old lots, or with suitable reference material, before or concurrently with being placed into service. For quantitative tests, perform reagent validation most reliably by assaying the same patient specimens with both the old and new reagent lots. For qualitative tests, the inspector should perform minimum cross-checking that includes retesting at least one known positive and one known negative sample from the old reagent lot against the new reagent lot. The laboratory should store reagents as required by the manufacturer. It should also document maintenance of storage temperatures, having the medical director or designee review on a monthly basis. The laboratory should not use reagents after their stated expiration date.

**Waived Test Requirements:** Certain checklist requirements are now different for waived tests versus nonwaived tests.

For waived tests, follow manufacturer instructions for:
- Test procedure and method validation
- Reagent storage, handling, and validation
- Quality control performance
- Calibration, calibration verification, analytical measurement range validation, and clinically reportable range

For waived tests, the following are not required (unless required by the test manufacturer):
- Lot-to-lot reagent validation
- Correlations among waived instruments and between waived instrument and main laboratory instrument
- Initial AMR validation and six-month interval validation

Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and nonwaived tests.

**Instruments and Equipment:** Checklist requirements concerning general instrument requirements are found in most checklists and address glassware and pipettes, automated pipettes and dispensers, thermometers and temperature-dependant equipment, centrifuges, and analytical balances.

- Glassware and pipettes: Volumetric flasks must be of certified accuracy (ie, Class A category of the National Institute of Standards and Technology [NIST]). All noncertified glassware must be checked for accuracy before being placed into service. Store volumetric pipettes separately as to size and type. Limit the use of disposable plastic pipettes to situations where the accuracy and precision of calibrated glass pipettes are not required.
- Check automated pipettes and dispensers for accuracy (by colorimetric, gravimetric,
volumetric, or other means) before being placed in service, and document results. Verify accuracy and reproducibility at laboratory-defined, periodic intervals. Limit the use of dispensers to measurements not requiring volumetric accuracy.

- Thermometers: An appropriate thermometric standard device of known accuracy (guaranteed by the manufacturer to meet NIST standards) must be available. Check all noncertified thermometers against an appropriate thermometric device before being placed into service. Check temperatures daily for all temperature-dependent equipment, such as refrigerators, freezers, water baths, and incubators. Specify acceptable limits for all temperature-dependent equipment.

- Only experienced personnel should clean, service, and recalibrate analytical balances. Mount balances so that vibrations do not interfere with the readings. Standard weights of an appropriate ANSI/ASTM class must be available for checking accuracy. Weights should be well maintained (clean, no rust). Document accuracy checks.

Consult the discipline-specific checklists for instrument and equipment requirements other than the general requirements discussed here.

**Laboratory General (GEN)**

The Laboratory General Checklist covers the entire laboratory and is used with each inspection. Issues such as management, personnel, specimen collection, computer function, inventory control, safety policies, QM, and general QC procedures are included. **Inspection of a discipline-specific area also includes the use of all applicable portions of the Laboratory General Checklist.** To accomplish this, each inspector must be knowledgeable about the Laboratory General Checklist requirements. To this purpose, the team leader, as applicable, should provide individual team members with copies of the appropriate sections of the Laboratory General Checklist.

**Ways the Discipline-Specific Inspector Can Assist the Laboratory General Inspector:** The inspector should do the following during the discipline-specific section inspection (eg, Microbiology, Immunology, Transfusion Medicine, Biorepository, etc) and discuss the findings with the laboratory general inspector at lunch or before the presumption conference.

1. Observations:
   - Posting of, or electronic access to, safety policies/procedures
   - Evacuation routes posted
   - Use of equipment and design of workplace that reduces the risk of ergonomic distress disorders and accidents
   - Elimination of exposure to blood borne pathogens during phlebotomy and laboratory testing
   - Use of non-latex rubber in gloves and other products and/or availability of reduced protein, powder-free latex gloves to protect patients and workers prone to latex allergies
   - Use and disposal of gloves at proper times, and the availability of hand-washing sinks or waterless skin decontamination dispensers throughout the laboratory
   - Use the appropriate personal protective devices when handling corrosive flammable biohazardous and carcinogenic materials
• Use of proper password security (for example, no posting of passwords near CRT terminals, no sharing of passwords, signing out when terminal is no longer in use, and no terminals placed in locations where clients, visitors, and nonessential staff cannot view content on screen)

2. Safety practices:
   • Use of personal protective equipment (PPE)
   • Segregation of contaminated trash/sharps
   • Use/disposal of gloves, hoods, and protective eyewear

3. Orphan testing: (ie, tests performed in multiple or unexpected locations); For example, if the laboratory performs Group A strep testing in locations other than microbiology or immunology, the discipline-specific inspector of the more traditional location should be notified; an inspector with appropriate expertise should inspect those tests.

4. Comparison of the lab's activity menu with to its procedure manuals: The laboratory may fail to report some tests to the CAP that it performs very infrequently.

5. Space: Situations that may endanger the quality of the test result or the health and safety of the laboratory employees should be cited. For instance, lack of bench-top space to open a procedure manual, storage that is underfoot, blocked hallways, etc.

**Personnel:** Instructions for sampling and evaluating laboratory personnel records are included in the Team Leader section of the Inspector's Inspection Packet and briefly discussed in the introduction to the Personnel section of the checklist. A chart detailing the personnel requirements is also included along with the laboratory's personnel roster. The inspector should use those guidelines to select and review personnel files. Technical personnel records must include a summary of training and experience; a copy of a diploma or transcript from the institution that qualifies the person to perform the level of testing to which they are assigned; state license and certification, if required by the state; a description of current duties (may be generic to a position); records of continuing education; records of radiation exposure where applicable; and work-related incident and/or accident records, and dates of employment. For non-US trained personnel, an evaluation by a foreign credentialing agency of education experience is required. Training and experience must be appropriate for the responsibilities of each person. If the qualifications of a supervisor (chief technologist or department head) are in question, describe the concerns in the Inspector's Summation Report. Directly discuss suggestions related to staffing levels and pathologist coverage issues with the laboratory director instead of during the summation conference.

An effective way to assess training and competency is to concentrate on any problems identified while inspecting a laboratory section. Such as the training and competency records of an employee involved in a problem to ensure that adequate training or retraining has taken place.

**The laboratory director must:**
• Meet the qualifications found in the *Standards for Laboratory Accreditation*
• Be a physician or doctoral scientist
• Have sufficient authority to implement the *Standards*
• Meet the requirements listed in the Team Leader Assessment of Director & Quality Checklist

**The biorepository director must:**
• Meet the qualifications found in the Standards for Biorepository Accreditation
• Have four or more years of full-time laboratory training and experience, of which at least two years were spent acquiring proficiency in biorepository operations and management.
• Have sufficient authority to implement the Standards
• Meet the requirements listed in the Laboratory General Checklist

Note: The director need not personally discharge all functions. Administrative functions may be delegated to qualified laboratory managers or supervisors. Medical and technical responsibilities may be delegated to other physicians and qualified laboratory personnel. When responsibilities are delegated, make available written documentation naming the designee. If the laboratory director is not qualified to direct any of the individual sections of the laboratory, those sections must be directed by a qualified individual.

Consulting Pathologist
When the director is not qualified as an anatomic pathologist, the laboratory must retain the services of a qualified consulting anatomic pathologist if any anatomic pathology testing is performed. A policy regarding the duties of the consulting pathologist must be in place.

The consulting pathologist must:
• Provide documentation of activities performed and a documented report with evaluation and recommendations in writing for each consultation visit as outlined in a contract or written job description.
• Visit the laboratory as often as required. The CAP does not define any specific frequency.
• Serve as a consultant to the medical staff and play an active role in the educational programs of the laboratory and institution.

Space and Facilities: Laboratory space is a component of quality and safety. Deficiencies in space are rated Phase II when they compromise the quality of work or the safety of the employees. All other significant limitations of space are to be cited as Phase I deficiencies. In either case, the ISR must detail the circumstances prompting the citation.

Specimen Collection: How specimens are collected and handled is critical for valid results. A laboratory must provide instructions for the collection and handling of specimens for all tests. If the laboratory accepts specimens collected by nonlaboratory personnel, a typical specimen collection area must be checked for availability of the specimen collection instructions. The inspector must ensure that the laboratory has reviewed its phlebotomy practices relative to specimen blood draw volumes and must verify through appropriate documentation that all personnel performing patient blood collection have been trained in the selection and use of equipment, supplies, and collection techniques.

The specimen collector must positively identify the patient before collecting a specimen. The inspector must verify that there is a documented, consistently followed system for unique patient sample identification from point of collection through all phases of specimen movement throughout the laboratory. The identifying label must be attached to the specimen container(s) at the time of collection, and not deferred until a later time.

The laboratory director or designee must review the specimen collection/handling manual at least every two years. Review is best accomplished by including this manual in a rolling 24-
month timeframe. In addition, the laboratory director must review and approve all substantial changes to the manual before implementation.

**Laboratory Transport Services:** Specimens received from locations outside of the facility in which the laboratory is located, as well as specimens referred by the laboratory to other locations, require transport to the testing laboratory. There must be a documented tracking system to ensure that all specimens submitted to the laboratory are actually received. The inspector must verify that the laboratory director has addressed the issues of specimen tracking, personnel training, packaging and labeling, monitoring of specimen quality, correction of problems, and improving the performance of clients or offices that frequently submit specimens improperly. The laboratory must package and ship infectious material in accordance with applicable federal, state, and local regulations.

Federal and international regulations mandate the proper packaging and transportation of infectious substances. Specific requirements are set forth by the US Public Health Service, the US International Air Transport Association, the US Department of Transportation, and the US Postal Service. These apply to **domestic transportation by land, air, or sea and to international air transportation.** All personnel at a sending facility must satisfactorily complete certified training in these requirements every two years. **Certified training requirements do not apply to personnel sending samples via private courier.**

**Personnel Competency Assessment:** The inspector will look for documentation indicating that the laboratory/biorepository has assessed annually the competency of each person to perform his or her assigned duties, in addition to the two semiannual evaluations required during the first year of testing. The laboratory/biorepository must have a documented corrective action plan to retrain and reassess employee competency when it identifies problems of employee performance. The inspector will look for evidence that the laboratory/biorepository reassessed competency and found it acceptable after it implemented the corrective action plan.

**Computer-Generated Reports:** A laboratory computer system located onsite must be clean, functional, and secure with adequate ventilation and firefighting equipment. The laboratory must have approved, documented procedures, including a downtime process. The laboratory must document hardware and software modifications, and it must validate that the system performs as expected. Training, maintenance, and ongoing calculation verification must be performed and documented. The system must have data backup capabilities, and the laboratory must be able to identify each person contributing to or editing a result, as well as the instrument involved. Results must be verified before being released. Any autoverification process must detect absurd values, and it must have a process for rapid suspension. The patient report must contain the name and address of the testing facility on the report, or be available if the report is viewed electronically. There must be documentation that in the judgment of the medical director the system meets both the needs of the laboratory and of CAP requirements.

**Review of Results:** A routine system must be in operation to detect clerical errors or unusual laboratory results and must provide for timely correction of any errors. Any computer system in the reporting process is subject to the requirement for this review. The QC policies and procedures must describe the review mechanism. No requirement for secondary daily review of patient test results is required.

**Confidentiality and Read-Back of Patient Orders and Reports:** Each laboratory must have a policy that personnel receiving verbal or phone orders must read back the entire order to verify
accuracy of transcription. The laboratory must also have a policy with respect to verification “read-back” of critical values that are communicated verbally or by phone. In addition, a documented protocol must be in place to ensure that patient data are accessible only to those health care personnel who are authorized to review test results. This applies both to results of in-house tests and to results received from outside reference laboratories.

**Record Retention:** The laboratory must retain specimen requisitions (including the patient chart or medical record, if used as the requisition), patient test results and reports, accession records, quality control records, proficiency testing records, and quality management records for a minimum of two years.

For data transmitted by computer interface (online system), it is not necessary to retain paper worksheets or printouts, so long as the computer retains the data for at least two years. If there is manual entry of patient result data, the laboratory must retain all worksheets or printouts for at least two years.

More stringent requirements for certain laboratory records (eg, in anatomic pathology, cytopathology, and transfusion medicine) may be found in the discipline-specific checklists. See Appendix G for complete information on record retention.

**Specimen Retention:** Retain serum and body fluid specimens (excluding urine) for at least 48 hours. Retain blood films, permanently stained body fluid slides, and microbiology slides for at least seven days. Additional detailed requirements or recommendations are found in section-specific checklists. Detail any deficiencies noted by the inspector in the ISR.

**Self-Inspection Documentation:** Laboratories must perform a self-inspection each year an on-site inspection by the CAP does not take place. The laboratory director must document the occurrence and findings of the self-inspection. If any deficiencies are found, the laboratory must document the corrective actions. Records of deficiencies noted during the self-inspection and appropriate corrective actions must be available for review by the inspector.

**Conducting the Safety Inspection**

**Introduction:** Requirements in the Laboratory General Checklist cover the general safety program for the entire laboratory/biorepository and must be answered for all laboratory/biorepository sections. Noncompliance with any of these requirements in any one section of the laboratory/biorepository represents a deficiency and must be cited in detail in the Inspector’s Summation Report Part B. Specific requirements related to safety features unique to an individual section will be found in the checklist for that section. Each member of the inspection team must inspect for safety hazards in that portion of the laboratory for which he/she is responsible.

**General Safety:** Procedures must be posted or otherwise available to all employees and instruction in these safe work practices must be documented as part of new employee orientation. The inspector should review the safety manual for completeness. Several items should be selected from the safety manual for interviewing an employee regarding knowledge about safety issues. Under US law, all serious accidents resulting in fatalities or in the hospitalization of three or more employees must be reported to the Occupational Safety and
Health Administration (OSHA) within eight hours. Reports of occupational injuries or illnesses that require medical treatment or result in time lost from work should be part of the laboratory’s QM program to avoid recurrence. This includes every needle stick or sharps injury. An inspector should ask about recent injuries or occupational illnesses and review the adequacy of the follow-up. Non-US laboratories must adhere to locally applicable regulations.

The current laboratory director or designee must review safety policies and procedures at least every two years. The laboratory director whose name is on the CLIA certificate must review all new or substantial changes. The laboratory must document that all laboratory personnel performing patient blood collection have been trained in proper selection and use of equipment, supplies, and collection techniques. This includes phlebotomists at remote sites owned and operated by the laboratory. OSHA now requires employers to select safer needle devices as they become available and to involve employees in identifying and choosing the devices. The updated standard also requires employers to maintain a log of injuries from contaminated sharps.

**Fire Prevention:** OSHA and the National Fire Protection Association (NFPA) standards may be used as references for fire prevention and preparedness questions. An accredited laboratory must have: 1) an automatic fire extinguishing system; or 2) be separated from a contiguous inpatient facility by fire-resistant construction that has a minimum rating of two hours (rating at 1.5 hours) and class B self-closing door assemblies rated at three-quarter hours; or 3) be located in buildings classified as "business occupancy." In all cases, a fire bell, public address system, or other alarm system must be audible in all sections. This includes lavatories, darkrooms, storage areas, and offices. **Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.** The inspector should ask employees if there are areas in which the alarm is difficult to hear. If there is any area where the alarm cannot be heard, the inspector should cite a deficiency. If there is any doubt as to the arrangement of the laboratory area or applicability to fire codes, the inspector should ask to see documentation that the local fire authorities have approved the current arrangement.

Fire drills must be held often enough that all laboratory personnel, from all areas and on all shifts, participate at least once per year. Class B portable fire extinguishers must be located in all areas where flammable or combustible liquids are stored or handled. There must be documentation that all personnel have been properly trained in the use of portable fire extinguishers. This must include actual operation of extinguishers that might be used in the event of an actual fire, unless the local fire authority prohibits this.

Ignitable liquids must be stored properly, and the Laboratory General Checklist specifies the US maxima by laboratory square footage, with consideration of safety cans, safety cabinets, and sprinkler systems.

**Electrical Hazards:** All laboratory instruments and appliances must be adequately grounded and checked for current leakage before initial use, after repair or modification, and when a problem is suspected. Those that are double insulated are exempted. Tasks may be delegated to biomedical and electrical engineers, but documentation must be present on inspection day, or a deficiency should be cited.
**Chemical Hazards:** The laboratory must evaluate and document the hazards associated with all chemicals present. The director must have a comprehensive signage and labeling system in use and applied throughout the laboratory. Warning signs must be posted where significant hazards exist. Each hazardous chemical must be labeled with the type of hazard and what to do if accidental contact occurs. Material safety data sheets (MSDS) must be on file for each hazardous chemical. It is acceptable for MSDS information to be electronically available to users, rather than in book format; there is no requirement for paper-based information. However, the MSDS file must be immediately available to all personnel at all times. The inspector may choose to select one or two hazardous chemicals found in the laboratory and question an appropriate employee about the safe work practices that relate to that substance. (For example, formaldehyde vapor is the most likely air contaminant to exceed the regulatory threshold in the clinical laboratory. Details of current regulations on formaldehyde monitoring are described in the checklist.)

For laboratories subject to US law, OSHA requires a comprehensive, documented Chemical Hygiene Plan (CHP) that includes all chemicals, regardless of type of risk, volume, or concentration. The plan must define storage requirements, handling procedures (including requirements for personal protective equipment), location of OSHA-approved MSDS (and other pertinent references), and the medical procedures to be followed if contact or overexposure occurs. Monitoring of vapor levels is required initially and whenever there is reason to believe that safe levels are routinely exceeded. Indications for monitoring must be defined. The CHP must specify the clinical signs and symptoms or the environmental conditions (such as a spill) that would indicate that overexposure has occurred. When such conditions exist, the CHP must describe the medical attention that will be provided. There must be evidence that the plan is reviewed annually for its effectiveness. Good laboratory practice includes making the CHP part of new-employee orientation and continuing education programs.

Chemical carcinogens, reproductive toxins, and other severely toxic chemicals are special concerns. The laboratory must evaluate the carcinogenic and toxicity potential of chemicals in the laboratory. This includes any chemical for which OSHA has specific occupational regulations (Formaldehyde, ethylene oxide, benzidine, and benzene are examples in this group that are reasonably likely to be found in laboratories.) The regulations also apply to any chemical that is believed to be potentially carcinogenic. This includes any substance so identified by the National Toxicology Program or by the International Agency for Research on Cancer. The director or designee must have completed this exercise before the inspection, and a deficiency should be cited if there is no documentation that such an exercise has occurred.

Provide personal protective equipment (PPE) appropriate to each hazardous task and mandate its use where appropriate. Such items include face shields, aprons, and gloves constructed of materials appropriate to the type of chemical handled. Plumbed eyewash fountains or the equivalent must be present and must be checked weekly. It is a deficiency if this equipment is present but access to it is obstructed. Check chemical fume hoods annually for proper function.

**Universal/Standard Precautions:** A system of universal standard precautions against the infectious hazards of blood and body fluids must exist. OSHA requires education of all

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1 29 CFR 1910.1200
2 29 CFR 1910.1450
3 29 CFR 1910.1001-1047
employees whose work involves the potential for contact with such substances. Those whose work likely involves contact with body substances must use gloves and other appropriate personal protective equipment (gowns, masks, and eye protectors, etc) in all situations when exposure is likely to occur.

If respiratory protection is needed because of potential exposure to an infectious agent by aerosol or droplet, personnel must use either a properly fit-tested National Institute for Occupational Safety and Health (NIOSH)-approved filter respirator (N-95 or higher) or a powered air-purifying respirator (PAPRS) equipped with high-efficiency particulate air (HEPA) filters. Accurate fit testing is a key component of effective respirator use. The inspector should cite a deficiency if the use of gloves or any other item commonly associated with universal precautions is not part of the laboratory's practice. Cleaning and disinfecting of disposable gloves for reuse are prohibited. Gloves, aprons, or laboratory coats and protective eyewear must be provided and are required for those activities likely to result in contamination of skin or mucous membranes. Use nonlatex or powder-free latex gloves to prevent hypersensitivity reactions to latex proteins. To prevent the transmission of potentially infectious agents, OSHA requires hand washing or antisepsis after glove removal. The Centers for Disease Control and Prevention (CDC) has published guidelines for hand hygiene. If hands are visibly dirty or contaminated with blood or proteinaceous material, the CDC recommends that the individuals wash their hands with soap and water. If hands are not visibly soiled, an alcohol-based waterless agent may be used.

Documented procedures detailing procurement, transportation, and handling of patient specimens (blood, body fluids, and tissue) to ensure that all specimens are submitted in an appropriately labeled and well-constructed container with a secure lid to prevent leakage during transport must be in place. If a laboratory uses pneumatic tube systems for transporting specimens, the laboratory must have procedures to respond to a spill, including appropriate decontamination measures. There must be documented procedures for handling spills of blood and other body fluids.

_Microbiological Hazards:_ The laboratory must have policies and procedures for assessing the occupational risk associated with exposure to infectious agents handled in the microbiology laboratory. The four biosafety levels for working with infectious agents are described in the CDC-National Institutes of Health (NIH) guideline (Biosafety in Microbiological and Biomedical Laboratories, US Dept. of Health and Human Services, Fifth Edition, January 2007). The laboratory must assess the biosafety level in which it operates and have policies and procedures appropriate to that level. Engineering and work practice controls appropriate to the biosafety level of the laboratory must be defined and implemented.

A functional biological safety cabinet (BSC) must be in use when culturing mycobacteria, fungi, and viruses. Biosafety in Microbiological and Biomedical Laboratories has an extensive discussion of cabinet types and their requirements. The inspector must determine if the laboratory has the appropriate equipment in use and if the equipment functions as intended. Certify each BSC annually. The inspector should review the records to ensure that the annual inspection included filter checks, flow rate measurements, and tests for seam integrity.

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4 HHS publication, 1993 stock #017-040-00523-7
**Waste Disposal:** The method for the disposal of all solid and liquid waste must be in compliance with applicable local, state, and federal regulations. There should be an ongoing program to minimize hazardous waste. The Environmental Protection Agency regulates the disposal of biohazardous waste such as specimen collection tubes, tissues, and bacteriology cultures. In general, all such waste must be either incinerated or disinfected appropriately before transportation to a sanitary landfill. All sharp waste, especially those contaminated with potentially infectious materials, should be discarded in puncture-resistant containers with tightly fitted lids.

The inspector should review the laboratory's documented policies and procedures for waste disposal and cite the laboratory if the manual lacks appropriate detail or omits important items. Technologists should be questioned regarding the segregation of wastes by hazard class at the point of generation to determine whether they understand the facility's policy. An inspector should visit the collection point at which wastes are collected for transportation to an off-site facility or for final disposition and try to determine the director's understanding of the final handling of all hazardous wastes.

**Radioactive Hazards:** Laboratories using radionuclides must manage them in a responsible manner. The Chemistry and Toxicology Checklist should be used to inspect laboratories that use radionuclides. There must be specific policies and procedures for the safe handling of tissues that may contain radioactive material (e.g., sentinel lymph nodes, breast biopsies, prostate "seeds," etc). Develop these policies and procedures in conjunction with the institutional radiation safety office and in compliance with any state regulations for the safe handling of tissues containing radionuclides. The policies and procedures should distinguish between low radioactivity specimens such as sentinel lymphadenectomy and implant devices with higher radiation levels.

**Disaster Preparedness:** The laboratory safety manual must have a section on "Internal and External Disaster Preparedness." A series of policies and procedures must be available to be followed in the event of a catastrophe such as fire, flood, electrical outage, or spill of hazardous volatiles (internal disaster), or a tornado, earthquake, or other mass-casualty situation (external disaster). The form that this portion of the safety manual takes is unique to each laboratory. There must be a comprehensive and workable documented evacuation plan for the laboratory. This plan must cover all employees, patients, and visitors and address the special needs of persons with disabilities. The inspector should cite a deficiency if it is believed that the laboratory's documented plans are inadequate.

**Ergonomics:** There must be a documented ergonomics plan. This plan should include training of employees about risk factors that cause musculoskeletal disorders, assessment activities to identify physical work activities or conditions of the job commonly associated with these difficulties, and recommendations for eliminating risk. Laboratory activity, workplace, and equipment (e.g. chairs, laboratory work stations, computer keyboards, and displays) should be designed to reduce the risks of ergonomic disorders and accidents.

Visit the CAP website Virtual Library of Audioconferences to hear the “Laboratory Safety” audioconference.
All Common (COM)

Why the CAP Created the All Common Checklist: The CAP created the All Common Checklist to improve how laboratories and inspectors plan and carry out inspections. The Common Checklist is a result of customers’ requests to reduce redundancy.

The all Common Checklist is not used in biorepository inspections. All BAP requirements are found in the Laboratory General and Biorepository Checklists.

Checklist Usage: The All Common Checklist is a reorganization of requirements that are similar or identical in all disciplines: they have been removed from the discipline-specific checklists. Requirements regarding proficiency testing, quality management general issues, and reagents, test method validation, reference intervals, procedure manual, and reporting of critical results have been grouped together and make up the content of the All Common Checklist. Some requirements from the Laboratory General Checklist have been relocated to the All Common Checklist where they can be better assessed in each department, versus being assessed one time for the entire laboratory.

Preparing to Inspect: The inspector must be familiar with the All Common Checklist and should review the checklist prior to the inspection along with the Laboratory General Checklist and any other applicable checklists. If the intent of any checklist requirement is not clear, the CAP technical staff can offer further explanation or interpretation at 800-323-4040 ext. 6065.

Proficiency Testing
Participation in proficiency testing (PT) is integral to the CAP’s accreditation programs, and is required for most tests for which the laboratory reports patient results (see Master Activity Menu with PT Options available on the CAP website at cap.org). There are three parts to the accreditation program’s PT compliance process: confirmation of enrollment, participation, and successful performance monitoring. In general, the Accreditation Program does not require PT for calculated analytes. However, there are a few exceptions listed in the Accreditation PT Enrollment Requirements (eg, Hemoglobin estimated, Hematocrit calculated and INR).

Enrollment and Participation: The CAP audits PT enrollment and participation continuously to ensure that accredited laboratories are enrolled and participate in PT as appropriate. These audits are based on the tests/activities that are reported by the laboratory to the CAP; therefore, they are present on the laboratory’s activity menu.

If enrollment in a CAP-accepted PT program (see glossary for the definition of CAP-accepted PT program) is not required for a particular test or if PT material is not available for a required event, the laboratory must perform and document an alternative method semiannually to assess its analytic performance for that test. Alternative assessment may include:

- Participation in a PT product supplied by the CAP or other providers
- Split sample analysis with reference or other laboratories
- Split samples with an established in-house method, assayed material, and regional pools
- Participation in ungraded/educational proficiency testing programs also satisfies this checklist requirement
- Clinical validation by chart review, or other suitable and documented means
Alternative assessment that allows for comparison of results with external laboratories (PT product, split sample with external laboratory, split sample with regional pool) may provide more information than split sample analysis using internal methods. The laboratory must define acceptable criteria for alternative assessment (eg, results within 10% of a reference method).

It is the responsibility of the laboratory director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

In some circumstances, certain tests may be performed intermittently, or for a short period of time (eg, tests done in support of research protocols, or tests related to seasonal diseases such as influenza). In such cases, either PT or alternative assessment must be performed when the test is put into production, and no less often than every six months while the test is in production.

Once a laboratory has enrolled in required PT, the CAP participation process continues to check that the accreditation program receives scores for the tests on a laboratory’s activity menu.

PT performance monitoring is a continuous process that looks for trends of unacceptable performance across four testing events. If the laboratory fails to meet the requirements of the CAP, the College’s PT Compliance Group will require the laboratory to provide documentation of corrective action. In the case of repeat unsuccessful PT performance, the laboratory may be directed to cease patient testing until it can present a plan of corrective action and demonstrate acceptable performance in proficiency testing and present a plan of corrective action. If the laboratory refuses to cease testing, its accreditation will be in jeopardy. The inspector uses PT performance to pinpoint areas for a more rigorous review during the on-site inspection.

It is helpful when records are organized such that evaluation reports and participant summaries are collated with original worksheets and instrument tapes, and all decisions and actions are clearly annotated. Participation in PT programs accepted by the Commission on Laboratory Accreditation is required for most analytes. Approval as a PT provider by CMS under CLIA does not automatically constitute acceptance by the College for purposes of accreditation. Not all CAP Surveys are required for accreditation. The PT enrollment requirements are listed in the CAP Surveys catalog and listed on the Master Activity Menu with PT Options available on the CAP website at cap.org. Any questions or requests for more information may be directed to the Proficiency Testing Compliance Group at CAP headquarters at 800-323-4040 ext. 6052.

The laboratory director must also ensure that no PT specimens are referred to another laboratory, even another laboratory within the same system or institution if it has a separate CLIA number. There may be no interlaboratory communications about PT samples with personnel outside the laboratory’s CLIA number. Although not entirely obvious, PT referral can occur unknowingly in the most practical laboratory application; for instance, a clinic lab sending a blood smear PT sample to the main laboratory for pathologist interpretation. The medical director must ensure that there is a well-established process for the handling of PT material, including circumstances that could be considered PT referral, so as to avoid jeopardizing its CLIA license.

Inspectors must review the performance of PT, including alternate assessment procedures that are used instead of formal external PT. Several items are included in the inspection packet to assist the inspector: The PT Performance < 100% Report, which lists all reported scores below
100% for the preceding six PT events, and the Laboratory Synopsis Report, which lists the performance of analytes that were repeatedly unsuccessful over the last four proficiency testing events, are among the items.

The laboratory must integrate all PT samples within the routine workload. Personnel who routinely test patient/client samples must analyze the PT samples, using the same testing protocols as for patient/client samples. The educational purposes of PT are best served by a rotation that allows all technologists to be involved. Records of these studies must be maintained and can be an important part of the competency and continuing education documentation in the personnel files of testing personnel.

Replicate analysis of any proficiency sample is acceptable only if patient/client specimens are routinely analyzed in the same manner. If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method.

The inspector may ask to see specific documentation of performance troubleshooting as well as clear evidence that a problem was corrected. Discussions could involve issues of QC performance during or adjacent to the same performance period, calibration accuracy, frequency or verification, and validation of the analytical measurement range. There must be documentation that any problems discovered through PT were identified and corrected and that the laboratory director or designee has reviewed all of the results and evaluations. In addition to reviewing follow-up on unacceptable results, the inspector must confirm that PT records are complete, that PT challenges have been handled like patient testing as closely as possible, and that any evident bias in PT results has been recognized and addressed.

Sometimes the required PT challenges are not graded. The reason should be footnoted on the Evaluation Report or made available from the PT provider. The laboratory must follow up whenever a PT provider intended to grade a required challenge. Suggestions for investigating nongraded PT results are given in Appendix I. The inspector will affirm that formal PT or alternative assessment is performed for every test performed on patients, and that all corrective actions are appropriate.

Investigating PT Failures and Biases:
- Check reporting forms and records of sample preparation and testing for mistakes.
- 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.
- Contact the instrument/reagent manufacturer for assistance.
- Repeat the PT challenge, if possible, using a different reagent lot or instrumentation system.

Corrective Action Following a PT Failure:
- Repeat instrument function or testing system verification.
- Increase the frequency of calibration.
- Revise or replace the analytic procedure.
- Design a process to double check clerical entries prior to submitting PT results. (However, if regular patient test results are reported as hand-written copy, then double-checking of
clerical PT entry is permissible only if regular patient reports are checked in the same manner).

- Retrain testing personnel in the proper procedures for sample preparation, testing, and reporting.
- Maintain clear records of all corrective actions taken.

For assistance with troubleshooting PT failures, refer to the CAP’s PT Troubleshooting Toolbox available through e-LAB Solutions.

For ideas on troubleshooting analytical issues, see CLSI Guideline GP27-A2 “Using Proficiency Testing to Improve the Clinical Laboratory [2007].”

**Procedure Manual**

Each section of the laboratory must have a complete procedure manual available to, and used by, personnel at the workbench. Elements of the procedure manual should include the following, as applicable: test principle, clinical significance, specimen type(s), required reagents, calibration, quality control, procedural steps, calculations, reference intervals, and interpretation. Laboratories may use CLSI document GP2-A4, *Clinical Laboratory Technical Procedure Manuals* (Wayne, PA: CLSI, 2002) as a guide, but need not copy its exact format. The specific style and format of procedure manuals are at the discretion of the laboratory director.

The inspection team should review the procedure manual in detail to understand the laboratory’s standard operating procedures and to ensure that all significant information and instructions are included. Direct observation of procedures during the on-site inspection allows the inspector to verify that actual practice matches the contents of the procedure manuals.

The use of a package insert provided by the manufacturer is not acceptable by itself in place of a procedure; however, such inserts may be used as part of a procedure if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed procedure must be detailed in the procedure manual. Quality control materials and acceptance criteria, reference ranges, critical values, and reportable ranges are aspects of a procedure that often result in customization of the written procedure by the individual laboratory. In all cases, procedure manual review must occur at the level of each procedure. One signature at the beginning of the procedure manual is not considered appropriate documentation of annual review.

Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that a complete manual is available for reference and the card file or similar system corresponds to the complete manual and is subject to document control.

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (ie, only authorized persons may make changes, changes are dated/signed [manual or electronic], and there is documentation of periodic review). There is no need to print a paper copy for the inspector if electronic procedures can be viewed during the inspection.
There must be documentation of review of all policies and procedures by the current laboratory director or designee at least every two years. The director is responsible for ensuring that the collection of technical protocols is complete and current, and a knowledgeable person has thoroughly reviewed it. If review is delegated, specify the designee(s) in writing. For new and significantly changed procedures the review/approve cannot be delegated. Paper/electronic signature review must be at the level of each procedure or as multiple signatures on a table of contents or listing of named procedures. A single signature on a title page or index of all procedures is not sufficient documentation that each procedure has been reviewed. A signature or initials on each page of a procedure is not required.

Critical Results

Critical Results Criteria/Notification – Establish criteria for immediate notification of a physician or other clinical personnel responsible for patient care for critical tests (glucose, potassium, calcium, etc). Indicate these criteria either in the procedure manual or in a separate policy manual. The bench technologists must be familiar with critical limits for procedures that they perform.

Critical results read-back – The laboratory must have a policy with respect to verification “read-back” of critical values that are communicated verbally or by phone.

Test Method Validation: The laboratory director/designee must sign a summary statement documenting review of validation studies and approval of each test for clinical use.

Method Performance Specifications – Sound laboratory practice requires full characterization of an assay before its use for patient testing, irrespective of federally designated test complexity and without regard to when it was first introduced by a given laboratory. The laboratory must have data on each test’s accuracy, precision, analytic sensitivity, interferences, and reportable range (ie, analytic measurement range [AMR]), as applicable.

For a laboratory subject to US regulations for unmodified US Food and Drug Administration (FDA)-cleared or approved tests, the laboratory may use data from manufacturers’ information or published reports; but the laboratory must verify outside data on accuracy, precision, and reportable range. For tests that are not FDA-cleared or approved, or for FDA-cleared/approved tests modified by the laboratory, the laboratory must establish accuracy, precision, analytic sensitivity, interferences, and reportable range, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable.

The laboratory must retain records of method performance specifications while the method is in use (plus two years), but in no case for less than two years.

Intermittent Testing: Tests that are taken out of production for a time (eg, seasonal testing such as influenza testing). A test is considered to be taken out of production when both of these conditions are met: 1) patient testing is not offered and 2) PT or alternative assessment, as applicable, is suspended.

Criteria for reinstatement of intermittent testing follow:
• PT or alternative assessment performed within 30 days prior to reinstatement
• Method performance specifications verified 30 days prior to reinstatement
• Competency assessment within 12 months prior to reinstatement
Additional areas covered under Method Performance Specifications are:
• Tests not FDA approved/cleared
• Analytic accuracy/precision
• Analytic sensitivity
• Analytic interferences
• Reportable range
• Method performance specifications availability
• Analytic methodology changes

Reference Intervals: The laboratory must establish reference intervals (normal values) for each analyte and specimen source.

The laboratory must also evaluate the appropriateness of the reference intervals and take corrective action, when appropriate.

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

Anatomic Pathology (ANP)

*Inspection of anatomic pathology is not limited to the contents of the Anatomic Pathology Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as areas Conducting the Inspection and Requirements Common to all Laboratory Sections.*

The Anatomic Pathology Checklist covers general anatomic pathology, surgical pathology, the histology laboratory, fine-needle aspiration specimens, immunohistochemistry, immunofluorescence, fluorescence in situ hybridization (FISH), digital image analysis, autopsy pathology, and electron microscopy. The inspector is expected to evaluate all aspects of quality control and quality management in the various sections of anatomic pathology. The inspector will consider procedural and technical activities (process or quality control), issues related to the professional role of the pathologist (quality management), and an evaluation of the quality of the diagnostic report (features of both quality control and quality management).

The inspector should spend at least several hours inspecting the anatomic pathology laboratory. Direct observation of technical procedures and careful review of quality management monitors are required elements of the inspection. Inspectors should be familiar with the CAP publication *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005* (formerly the *Quality Improvement Manual in Anatomic Pathology*).

The on-site inspection will require the inspector to review the reports and slides of at least 10 surgical pathology cases (preferably of various complexities and types), five autopsies, and example slides of all routine and special stains offered. Laboratories that do not file slides on
site (eg, "read-only" laboratories) must retain a sample of slides on site on all days when the laboratory is subject to its regular on-site inspection. The sample must, at a minimum, include all slides accessioned over a continuous two-week period within the previous two years.

Because the sections of anatomic pathology ultimately deal with subjective, consultative medical opinion, the inspector should recognize that different laboratories vary in their design and implementation of overall quality management programs. It is important that the inspector does not insist on "my way," but rather make an effort to determine whether the programs and procedures in place achieve the fundamental goal of providing the referring physician with an accurate, timely, and clinically relevant diagnostic report based upon the interpretation of optimal technical preparations.

**Quality Management (QM) Program:** The preamble to this part of the checklist designates the activities that must be included. The design of the program is the responsibility of the laboratory director. The laboratory must have a clearly defined, documented QM program that includes active monitoring of laboratory activities. Evaluation of the results of monitoring must be documented. Quality monitors or indicators may differ among laboratories. The QM program must ensure quality throughout the preanalytic, analytic, and postanalytic phases of testing—including specimen identification, preservation, transportation, and processing—and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory’s systems and identifying opportunities for system improvement. The laboratory must document the corrective/preventive actions taken based on data from its QM program. While the type of program will vary according to the staff size and the volume and type of diagnostic material, the basic quality control/quality management principles of description, organization, systematic review, documentation, communication, and turnaround time must apply. Technical and procedural quality controls are integral components of comprehensive quality management and should be shared with the responsible pathologist(s).

**Quality Control:** These requirements address issues concerned with collection and accessioning of specimens, the surgical specimen examination area, and procedures related to gross surgical specimen examination. Although not solely a quality control issue, intraoperative consultation (rapid diagnosis or frozen section) is addressed in this portion of the checklist. There is also a section for fine-needle aspiration (FNA) specimens that are processed and reported in the surgical pathology laboratory; this section does not apply if FNA specimens are evaluated for adequacy only, or if they are screened by a cytotechnologist. (The Cytopathology Checklist is used in the latter case.)

Review of the quality of surgical pathology reports is considered under Quality Control. Requirements also address the need for clear and concise gross descriptions that contain adequate information about the lesions present. The final diagnosis should correlate with the descriptions, provide sufficient information to contribute to patient management, and be available in a timely fashion. The laboratory should have a mechanism to correlate the results of specialized studies (eg, electron microscopy, immunohistochemistry, nucleic acid probes, cytogenetics, etc) with the morphologic diagnosis, and to **reconcile potentially conflicting data**, when appropriate.
**Histology:** Quality control items include evaluation of procedure manuals, histologic preparations, special stains, instruments, and equipment. Requirements pertaining to immunohistochemistry are included in this section of the ANP Checklist.

There are several key areas to focus upon during the inspection of immunohistochemistry (IHC), including the oversight functions of the responsible pathologist, annual review of procedure manuals, and participation in a peer education program (e.g., CAP Educational Anatomic Pathology Program for immunohistochemistry [Survey MK]). The inspector should ensure that there is documentation of corrective action and pathologist review of quality control problems, as well as validation of new antibody lots and of procedures that were implemented since the last on-site inspection.

A comprehensive discussion of positive and negative controls in immunohistochemistry can be found in the checklist (see ANP.22550 and ANP.22570). Internal positive controls are acceptable (for instance, staining of vascular smooth muscle by smooth muscle actin), but the procedure manual must indicate the manner in which such controls are used for each antibody affected. Negative controls should include both a *reagent* control (patient tissue processed without the primary antibody) and a *tissue* control (absence of staining in tissues that lack the antigen).

If the laboratory is engaged in IHC for predictive markers such as HER2 or ER/PgR, the report should include information on specimen processing, the antibody clone, and the scoring method used. If the lab performs HER2 or ER/PgR testing, either by immunohistochemistry or by fluorescence in situ hybridization or ER and/or PgR by immunohistochemistry, it must participate in proficiency testing (PT), and all standard requirements for PT must be observed, including integration with the routine workload, ongoing evaluation of results, and a prohibition of both interlaboratory communication and referral of specimens. However, if the laboratory routinely interprets specimens that it refers for processing in another laboratory, then it should send the IHC PT slides to that lab for processing only, and interpret the slides as per usual. However, any laboratory that performs HER2 testing by fluorescence in situ hybridization (FISH) interpretation only may not send PT samples to another facility for hybridization. Laboratories that only interpret HER2 by FISH are required to perform alternative assessment as assurance that their testing process and interpretation are accurate. These data should be reviewed during on-site inspections.

There are specific requirements for assay validation, including comparison with a clinically validated method with an appropriate number of specimens, and revalidation whenever there is a significant change in procedure. The laboratory must control and document length of fixation and must use American Society of Clinical Oncology (ASCO) scoring criteria.

The inspector should assess the quality of the immunostains by direct review of immunostained slides. Sample pathology reports representative of the reporting format used for immunostains should be reviewed along with the slides. The inspector should verify that the reports contain all required elements specified in the checklist. (Visit the CAP website for Virtual Library of Audioconferences to hear “Test Validation: A Brave New World for Anatomic Pathology.”)

The inspector should meet with the supervisor and, if needed, with the pathologist serving as medical director, to ascertain the regulatory classification types of reagents used in the
laboratory. Primary antibodies used for clinical immunohistochemistry testing are classified in one of four regulatory categories:

Class I ASR  
Class I for In Vitro Diagnostic Use (INVDU)  
Class II for INVDU  
Class III for INVDU

Most antibodies used for clinical IHC are Class I ASR or Class I for INVDU. The checklist contains an extensive discussion regarding the use and reporting of ASRs (see ANP.12425).

Regardless of the regulatory class of reagent, the laboratory is required to perform in-house validation and documentation of each antibody, even for Class II and III reagents. Positive and negative controls must also be validated. It is well recognized that IHC analytical testing represents a key part of a total analytical system that includes a variety of complex pre- and postanalytical controls.

**Digital Image Analysis:** The definition of digital image analysis is the computer-assisted detection or quantification of specific features in an image following evaluation and processing of the image. This includes DNA analysis, morphometric analysis, and FISH.

There must be documentation that the system has been validated and acceptable specimen conditions defined. If the system is not FDA approved (or is FDA approved but modified by the laboratory), the inspector must verify that the laboratory has established the accuracy, precision, analytic sensitivity, interferences, and reportable range of the test procedure. If the system is FDA approved and unmodified, the laboratory only has to verify these factors. There must be a calibration procedure and documentation of calibration results. Controls at multiple levels must be tested daily by the operator(s) of the system. A negative control must be used to define a threshold for positive-staining cells. Controls must be verified for acceptability and organized to detect problems. Control results must be reviewed and assessed monthly by the laboratory director or designee.

When performing DNA staining, there must be documented criteria for acceptability of histograms for interpretations. There must be appropriate internal and external controls of known DNA content evaluated with each specimen or batch of specimens and criteria must be established for identification of an aneuploid cell population.

Digital image analysis reports must include an interpretation by a responsible pathologist. The final report must include a reference range or a comment regarding the expected result for the patient and the site of the specimen, if applicable. The report must also include the specimen source, name of vendor, system used, antibody clone and source, the antigen retrieval method, limitations of the test result, name and address of the laboratory where staining and image analysis were performed, and the name of the person performing the analysis.

Further information can be obtained at the FDA website at [accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/ShowCFR.cfm](accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/ShowCFR.cfm). Visit the CAP website for Virtual Library of Audioconferences to hear “Test Validation: A Brave New World for Anatomic Pathology.”
Laboratories that interpret and report the results of HER2 or ER/PgR testing by IHC in which staining (and imaging, as applicable) are performed at an outside laboratory are required to enroll in PT but must ensure that they only receive back the stained PT slide or an unanalyzed image of the stained PT slide. The laboratory must ensure that the outside laboratory does not send back any quantitative image analysis data; the latter would constitute PT Referral by CMS, and this can have serious consequences.

**Safety:** Safety requirements emphasize the adequacy of ventilation and the handling of infectious tissues and other contaminated materials in areas of specimen handling and processing, including special precautions related to Creutzfeldt-Jakob disease. The inspector should review relevant requirements from the Safety section of the Laboratory General Checklist to ensure that the Anatomic Pathology section is in compliance.

The laboratory must perform an initial formaldehyde monitoring procedure in all areas where this reagent is used and when exposure levels are most likely to be high (for instance, when changing reagents in the tissue processor, or when discarding specimens). Monitoring must include both the eight-hour time-weighted exposure and the 15-minute short-term average exposure results. Further periodic formaldehyde monitoring is mandated if results of the initial monitoring equal or exceed 0.5 ppm (eight-hour time-weighted exposure, the “action level”) or 2.0 ppm (15-minute exposure, STEL). The laboratory may discontinue periodic formaldehyde monitoring if results from two consecutive sampling periods taken at least seven days apart show that employee exposure is below both the action level and the short term exposure limit, and (1) no change has occurred in production, equipment, process, or personnel or control measures that may result in new or additional exposure to formaldehyde, and (2) there have been no reports of conditions that may be associated with formaldehyde exposure.

The laboratory must monitor xylene vapors initially, but there is no requirement for periodic monitoring of xylene unless any personnel report signs or symptoms indicating potential exposure to fumes.

**Results Reporting:** The inspector should review 15–20 completed reports for adequacy of specimen descriptions and diagnoses, inclusion of sufficient information for grading and staging of neoplasms, and correlation of special studies (e.g., immunohistochemistry, electron microscopy) with the final diagnosis. Reports should be signed (either electronic or physical signature) by the reporting pathologist, and the laboratory should have a procedure that ensures and documents that the reporting pathologist has reviewed and approved the completed report before its release. The laboratory also should have a policy regarding the timely communication and documentation of significant or unexpected diagnostic findings.

**Autopsy Pathology:** Items emphasized include timely reporting of both preliminary and final diagnostic findings, and policies regarding proper conduct of autopsies on patients with known or suspected infectious diseases. In addition, the important role that the autopsy plays in quality assurance must be addressed, including both the quality of autopsy performance itself and the manner in which it may enhance the quality of patient care. The laboratory should monitor safety issues (see above).

Practical suggestions for implementing and documenting these and other measures can be found in the CAP *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005.*
Electron Microscopy: The initial part of this section is concerned with quality control issues such as procedure manuals, specimen collection, specimen preparation, instruments and equipment, reports, and records. This is followed by a review of the physical facilities and safety items that pertain specifically to the electron microscopy service.

Physical Facility: Special attention should be given to the suitability of space and environment for technical procedures and for microscopic study, and conditions for preservation and storage of paraffin blocks and slides.

Biorepository (BAP)

Policies and Procedures: The Biorepository must have the procedure manual available to staff members in the work area. Procedures must be reviewed at least every two years. There must be a policy on confidentiality of specimen donors. The biorepository director must review and approve all new and substantially changed procedures before implementation. There must be documentation that the staff members are knowledgeable about the content of their procedures.

Specimen Handling: The biorepository must have policies describing the types of specimens that can be submitted to the biorepository. There must be a quality control process to ensure the quality of stored specimens. The biorepository must closely monitor and document storage temperatures including any excursions. There must be policies for safe handling of specimens that are potentially infectious, policies for the release of surgical specimens for research, and policies for relabeling and de-identifying specimens. Biorepository staff members must have specimen rejection criteria, an informed consent process, and a specimen tracking mechanism. Specimen identification must be maintained through each step of processing and slide preparation and each specimen must be identified uniquely when received into the biorepository.

Storage, Preservation, and Disposition: Tissue storage conditions must be defined in the procedure manual for each specimen type, including a protocol for returning specimens into storage after issuance. There must be documentation that all specimens were stored at the appropriate temperature for that specimen type. Preanalytic disposition variables must be captured to ensure they are not impacting specimen quality. Key elements of processing and preservation must be documented in the biospecimen QA report when available. Key elements related to processing and preservation must be documented for fluid biospecimens. The biorepository must have a policy detailing disposition of specimens consistent with regulations.

Specimen Processing: The biorepository that use specimen processing methods such as DNA/RNA Extraction/Amplification, Digital Image Capture, Tissue Microarray, Laser Capture Microdissection and Cell Fractionation must have procedures for each of these methods in use. There must be systems in place to maintain proper specimen identification. The method specific requirements can be found in the Biorepository Checklist.

Instruments and Equipment: The biorepository must have a schedule for servicing, checking and maintaining all instruments and equipment. Service, repair and maintenance records must be available to the staff members.
**Storage Equipment:** The biorepository must have procedures detailing storage conditions for all specimen types, calibration of storage equipment, transfer of specimens, and an emergency response plan. There must be evidence that high and low temperature set points have been established and documented for each storage environment. Refrigerator and freezer temperatures must be documented daily. Specimen containers must be approved for their intended use.

**Temperature Monitoring and Alarms:** The biorepository must have a thermometric standard device (NIST thermometer). All noncertified thermometers must be checked against the thermometric standard device before initial use. Temperatures must be checked daily, including the storage unit and location. Temperature alarm limits must be established for each unit, taking into account adequate time to respond to the alarm. Storage equipment must have an emergency power supply. Each storage unit must have an audible alarm that is continuously monitored 24 hours per day, with a validated response system. The alarms must be periodically checked at both high and low temperature limits. The biorepository must have a contingency plan in place to monitor the storage unit if the alarm system fails.

**Information Technology Systems:** The biorepository must have documentation for its information system that the programs have been tested and approved by the medical director. Biorepository personnel must correct and document software. There must be a way to track and identify all individuals who have made software modifications. There must be training on the information system and its software initially and after system modifications or if a new system is installed. The system must have appropriate security that includes mandatory time-out and password protection. The system should protect data and services from loss. The system should allow for the retrieval of archived data. There must be interface security if other computer systems can access the biorepository system to prevent unauthorized access to data.

**Inventory System:** The biorepository must document its inventory system, which should include privilege levels. The inventory system must be able to track multiple criteria. The system must include an audit trail. The biorepository must document discrepancies that have been reconciled prior to distribution. It should perform a quality check before distribution.

**Informed Consent:** The biorepository must have informed consent criteria. All required approvals must have been documented and appropriate consent completed if there is no waiver of consent. It should have policies ensuring privacy and confidentiality.

**Chemistry and Toxicology (CHM)**

*Inspection of chemistry and toxicology is not limited to the contents of the Chemistry and Toxicology Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*

The Chemistry and Toxicology Checklist (CHM) addresses:
• Basic chemistry procedures, typically performed on automated and semiautomated instruments, including blood gas analysis and oximetry
• Toxicology testing, including all screening and/or confirmatory testing for drugs of abuse, legal alcohol analysis and other toxicology tests, regardless of methodology
• Therapeutic drug monitoring (TDM) regardless of instrument or method
• Specialized tests such as prenatal screening for fetal anomalies; cystic fibrosis screening; immunoassays (including testing for hepatitis and other viral markers); assays performed by flame photometry, atomic absorption, chromatography and mass spectroscopy, and electrophoresis

If radioimmunoassay is performed, the inspector must review the radiation safety manual and personnel records for documentation of radiation exposure. The inspector should ask to see the facility’s radiation license. The laboratory may be regulated under a general license if the facility uses only small amounts of radioactive materials. This is commonly the case when commercially prepared kits are used. The amounts per kit must be documented. Alternatively, the facility may hold a specific license granted to it by the Nuclear Regulatory Commission. A specific license has all the elements of a general license as well as additional items that have been tailored to the requirements of that facility. The checklist includes several requirements that commonly apply to facilities with a specific license; however, the inspector should inspect such a facility according to the actual requirements listed in that specific license.

Laboratories performing only blood gas testing now use the CHM Checklist, but will receive requirements related only to blood gas and oximetry testing, as applicable. Blood gas quality control requirements are at least one level for pH, pCO₂, and pO₂ every eight hours of patient testing, with a low and high level required each day of patient testing. Automated instruments must internally calibrate at least once every 30 minutes of use, or a control sample must be run with every patient.

Some laboratories may choose to perform certain tests exclusively for legal purposes (eg, alcohol for traffic law enforcement, and criminal justice and medical examiner systems). In this case, the performance of legal testing must meet forensic, not clinical laboratory, standards. These forensic standards include the requirements for chain-of-custody protocols for specimens and aliquots, specimen seals, increased specimen and record security, appropriate confirmation testing, and a certifying review process.

Certain clinical tests have a higher potential for being involved in a legal proceeding, such as blood alcohol tests for motor vehicle accident patients and drugs of abuse tests for patients undergoing drug treatment or neonates suspected of drug exposure in utero. Therefore, a laboratory may choose to conduct these clinical tests using procedures and policies that meet both forensic and clinical laboratory standards. It is not a CAP requirement, however, to conduct any clinical testing using the standards of legal testing; it is an administrative decision to do so. Toxicology testing for diagnosis, treatment, or other clinical purposes must meet only clinical laboratory practice standards.

Requirements that relate specifically to legal or forensic toxicology testing requirements are in the Legal Testing section of the Chemistry and Toxicology Checklist. The requirements address chain-of-custody, data review, reporting, and security. The inspector must use the Chemistry

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5 10 CFR31.11
and Toxicology Checklist to cover positive screening results that are released as unconfirmed per client request, even if the laboratory is enrolled in the CAP Forensic Drug Testing (FDT) accreditation program. The inspector should pay particular attention to chain-of-custody documents, and restriction of access to specimens and forensic data in the laboratory computer system, as well as establishment of defined cutoffs and whether or not QC adequately challenges these cutoffs.

The chemistry laboratory usually is the largest department in a full-service laboratory, and its test menu usually is extensive. Time does not permit a detailed review of every procedure, of calibration of every pipette and thermometer, or an extensive inspection of every quality control record. The emphasis should be selective, focusing on the areas of both highest and lowest volume, as well as on areas where test results most impact patient care (eg, hCG, HIV, glucose), and on any apparent problem areas. It usually is more instructive to review the records for 10 tests comprehensively than to review the records for 50 tests superficially.

The Chemistry and Toxicology Checklist addresses laboratory equipment such as pipettes, glassware, thermometers, centrifuges, analytical balances, spectrophotometers, and other basic analytic systems. See page 41 in this manual “Inspecting the Laboratory Sections, Requirements Common to all Laboratory Sections, Instruments and Equipment,” for a more detailed discussion of equipment requirements. Equipment or instruments used for primary analysis of patient samples should be thoroughly examined. When analytical systems are maintained for backup purposes and are infrequently utilized, then evaluation should be directed to system maintenance and the adequacy of correlation between analyzers.

**Calibration, calibration verification, and analytical measurement range (AMR):** Verification records should be examined closely to ensure that the analytical system stability meets the claims of the instrument/reagent manufacturer. Calibration should be performed according to manufacturer instructions. Calibration or calibration verification must be performed every six months. If excessive time has elapsed between calibrations, a separate calibration verification process is required. Analytical measurement range verification must be performed at a minimum of every six months with three concentrations of material that span the low, mid, and high portions of the AMR. AMR verification is not required if the calibration process utilizes at least three calibrators that span the AMR and if calibration is performed more frequently than every six months.

**Maximum Dilution/Concentration:** For analytes that may have results falling outside the limits of the AMR, the inspector should check to see that the laboratory procedure specifies the maximum concentration or dilution that may be performed to obtain a reportable numeric result.

Establishment of allowable dilutions and concentrations is performed when a method is first placed into service and is reviewed annually thereafter as part of the procedure manual review by the laboratory director or designee.

The laboratory must have documented procedures for all required maintenance, with frequency and schedule noted. There must be evidence of results of all required maintenance.

**Waived Test Requirements:** Certain checklist requirements are now different for waived tests versus nonwaived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements section of this accreditation manual for specific details.
Clinical Biochemical Genetics (CBG)

**Inspection of biochemical genetics is not limited to the contents of the Clinical Biochemical Genetics Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.**

**Checklist Usage:** The Biochemical Genetics Checklist covers most aspects of clinical biochemical genetic testing performed for the diagnosis of inborn errors of metabolism (IEMs), including (but not limited to) the analysis of amino acids, organic acids, enzymes involved in intermediary metabolism, carnitine and acylcarnitines, acylglycines, CSF neurotransmitters, sugars, glycosaminoglycans, and glycoproteins. Biochemical tests for the identification of heterozygotes of IEMs and newborn screening for IEMs are also covered. In most cases results of biochemical genetic tests requires interpretation by an individual knowledgeable about IEMs and experienced with their laboratory diagnosis, such as individuals certified in clinical biochemical genetics by the American Board of Medical Genetics. The inspection of laboratories performing biochemical genetic testing requires the Biochemical Genetics Checklist.

**Inspector Requirements:** Inspection of a biochemical genetics laboratory requires special knowledge of IEMs and the laboratory procedures used for their diagnosis. The inspector should have working knowledge of high-performance liquid chromatography (HPLC) and/or automated amino acid analyzer, gas chromatography-mass spectrometry, tandem mass spectrometry, and enzymatic methods for the diagnosis of IEMs. He/she should be familiar with the use of these procedures and instruments for the analysis of amino acids, organic acids, carnitine, acylcarnitines, glycosaminoglycans, and enzymes involved in intermediary metabolism, and newborn screening for IEMs.

**Preparing to Inspect:** The inspector must be familiar with the Clinical Biochemical Genetics Checklist and should review the checklist prior to the inspection along with the Laboratory General Checklist and the All Common Checklist. If the intent of any checklist requirement is not clear, the CAP technical staff can offer further explanation or interpretation at 800-323-4040 ext. 6065.

**Specimen Collection and Handling:** Specimen collection and handling are critical, even if the patient and the testing instruments are near one another. Specific instructions for the proper collection and handling of specimens must be made available to anyone collecting patient test materials that are sent to the laboratory.

**Calibration and Standards:** The laboratory should examine verification records closely to ensure that the analytical system stability meets the claims of the instrument/reagent manufacturer. Calibration should be performed according to manufacturer instructions. Calibration or calibration verification must be performed every six months. If excessive time has elapsed between calibrations, a separate calibration verification process is required. Analytical measurement range verification must be performed at a minimum of every six months with three concentrations of material that span the low, mid, and high portions of the AMR. AMR.
verification is not required if the calibration process utilizes at least three calibrators that span the AMR and if calibration is performed more frequently than every six months.

The laboratory must be able to demonstrate ongoing system accuracy and stability. This is particularly important if the laboratory has elected infrequent quality control systems. Appropriate multilevel control specimens must be used at least daily on days when patient specimens are tested.

The laboratory must have documented procedures for all required maintenance, with frequency and schedule noted. There must be evidence and results of all required maintenance.

Controls: Controls are used to ensure that a test system is performing correctly. Traditionally, controls are samples that act as surrogates for patient/client specimens, periodically processed like a patient/client sample to monitor the ongoing performance of the entire analytic process. Under certain circumstances, other types of controls (electronic, procedural, built-in) may be used.

Areas that require review by the inspector are:
• Daily QC
• QC acceptable range verification
• Numeric QC data
• QC corrective action
• QC handling
• QC verification
• Monthly QC review

Method and Instrument Systems: There are four main methods used in clinical biochemical genetics:
1. Enzymatic methods for metabolic disorders
2. GC/MS
3. MS/MS
4. HPLC or automated amino acid analysis

Equipment Maintenance: A variety of instruments and equipment are used to support the performance of analytical procedures. All instruments and equipment should be properly operated, maintained, serviced, and monitored to ensure that malfunctions of these instruments and equipment do not adversely affect the analytical results. The procedures and schedules for instrument maintenance must be thorough and as frequent as specified by the manufacturer.

Laboratory Safety: The inspector should, in addition to reviewing the relevant requirements from the Safety section of the Laboratory General Checklist, ensure that the radiation safety precautions are in place.

Cytogenetics (CYG)

Inspection of cytogenetics is not limited to the contents of the Cytogenetics Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the
The Cytogenetics Checklist is used for the inspection of laboratories performing cytogenetic studies of amniotic fluid, bone marrow, chorionic villi, chromosome breakage, blood lymphocytes, solid tumors, and nonneoplastic tissues. The laboratory may use one or more of conventional, fluorescence in situ hybridization (FISH), and microarray techniques.

**Inspector Requirements:** Cytogenetics inspectors should be qualified pathologists, cytogeneticists, or cytogenetic technologists who are actively involved with or have extensive experience in the practice of cytogenetics and are knowledgeable about current CAP checklist and corresponding CLIA requirements. A list of cytogenetics specialty inspectors is provided to the inspection team leader in the Inspector’s Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP inspector database specialist at 800-323-4040 ext. 7380 for the names of additional qualified inspectors. If the team leader has a potential inspector that meets the defined qualifications who is not on the specialty list, the inspector can submit his or her qualifications to be evaluated for addition to the specialty list by contacting the LAP Inspector Database Specialist.

**Inspection Process:**

- Observe the processes of specimen accessioning, culture, harvest, slide preparation, microscopy, and reporting, mailing, and filing. Check for safe work practices.
- Select at least 10 recent representative studies and evaluate the laboratory’s practice with regard to test requests, specimen processing, records, and report standards.
- Meet with the laboratory director and clarify any discrepancies noted between written procedures and observed laboratory practices. Discuss any deficiencies or recommendations.

**Procedures and Test Systems:** All cultures must be set up in duplicate or established independently. Duplicate amniotic fluid and chorionic villus cultures must be harvested independently. Request to review the records of failed cultures and suboptimal analyses. Look for evidence that the reasons for culture failures have been investigated and actions taken when improvement opportunities occur. For prenatal testing, there should be an attempt to follow-up each abnormal amniocentesis result at the time of parturition or termination.

**Cells Counted and Analyzed:** The minimum number of cells to be studied is a function of sample source, culture technique, and other factors. Specific requirements are addressed in various checklist items.

**Band Resolution:** The laboratory should use a defined and reproducible method for identifying band levels. Band resolution is expected at 550 bands for appropriate blood samples, especially in cases of mental retardation, dysmorphology, and birth defects. Resolution at the 400-band level is the minimum acceptable standard for constitutional cases. Lower resolution should be exceptional and explainable.

**FISH:** Review a sampling of FISH cases and controls, evaluation signal, background, and morphology. There must be documentation of validation of commercially available and home-brew probes. If FISH testing is performed using Class I analyte-specific reagents (ASRs) obtained or purchased from an outside vendor, the patient report must include the disclaimer statement required by the FDA.
**HER2:** The inspection checklist contains requirements from the ASCO/CAP “Guideline for HER2 Testing in Invasive Breast Cancer” relating to fixation of specimens, validation of HER2 assays, and reporting of results with ASCO/CAP scoring criteria. The ASCO/CAP guideline may be found at [cap.org](http://cap.org/) and may be periodically revised.

**Genomic Copy Number Assessment—Microarray:** Review validation data for implementation of new methods and ongoing documentation of continuous quality monitoring of assay performance. The quality of critical assay components, such as chips and labeling reagents, should be verified prior to use.

**Reports:**
- The cytogenetics report must include the name and address of the testing laboratory, the patient name and unique identifying number, patient date of birth, physician name, specimen source, date of specimen receipt, date of report, clinical indication for the test, cells counted, analyzed, and karyotyped, band resolution and methods, comments on specimen adequacy, if indicated and the signature of a qualified cytogeneticist as defined in CYG.50000.
  - Review several normal and abnormal cases and investigate how the laboratory handles a sample received without clinical information or diagnosis.
  - Photographs and other records must substantiate the final interpretation of each case.
  - Investigate how abnormal results are communicated to referring physicians.
  - The most current edition of the *International System for Human Cytogenetic Nomenclature (ISCN)* must be used correctly in the final report for conventional cytogenetics.
  - FISH result interpretation should be made with reference to internal, historical, or concurrent controls.
  - Errors occurring in the final report (such as typographical sex-designation errors) must be thoroughly investigated and the results of the investigation documented.
  - Preliminary reports, especially verbal or telephone reports, must be documented on the final report.
- The final report should contain recommendations for genetic counseling and/or additional studies of the patient and/or family members, when appropriate.
  - Report turnaround times: 90% of reports must be available as follows:

    | Test                                      | Final       |
    |-------------------------------------------|-------------|
    | Amniotic fluid and chorionic villi analyses | 14 days     |
    | Nonneoplastic blood                       | 28 days     |
    | Stat chromosomal analysis                  | Preliminary: 3 calendar days |
    | Stat chromosomal analysis                  | Final: 7 days |
    | Nonneoplastic, fibroblast                 | Final: 6 weeks |
    | Neoplastic blood and bone marrow          | Final: 21 days |

**Cytopathology (CYP)**

*Inspection of cytopathology is not limited to the contents of the Cytopathology Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.*

The inspector should be a pathologist or supervisor-qualified cytotechnologist actively involved or experienced in the current practice of cytopathology and conversant with contemporary...
quality management practices and the CLIA regulations pertinent to cytopathology. In addition to the checklist, it is helpful for the inspector to review the CAP’s *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005* (formerly the *Quality Improvement Manual in Anatomic Pathology*) and the CLIA regulations. The inspector should plan to spend several hours inspecting the cytopathology section regardless of case volume. The on-site inspection will require documented review of case (slide) material, direct observation of technical procedures, and careful review of quality management practices. Laboratories that do not file slides on site (e.g., “read-only” laboratories) must retain a sample of slides on site on all days when the laboratory is subject to its regular on-site inspection. The sample must, at a minimum, include all slides accessioned over a continuous two-week period within the previous two years.

The Cytopathology Checklist (CYP) has been organized to streamline the inspection process by creating specific sections for general cytopathology, gynecologic cytopathology, and nongynecologic cytopathology.

**Personnel and Screening:** The inspector must review the qualifications of the pathologist director (technical supervisor), general supervisor, and cytotechnologist(s), and assess documentation that affirms performance of their respective responsibilities, as outlined in the checklist. The cytopathologist may serve as the general supervisor. The qualifications for general supervisor can be found in the checklist (CYP.08100, and in 42CFR493.1469). The general supervisor, as designated by the laboratory director, is responsible for day-to-day supervision and oversight of the laboratory operation and personnel who perform testing and reporting of test results. Specific requirements are in the checklist (CYP.08200).

Sufficient qualified personnel and space must be available to handle the case volume and variety. The inspector should evaluate whether the facility provides adequate space and a suitable environment for screening, together with applicable quality control and quality management data, when judging the adequacy of cytopathology laboratory staffing. Although CLIA establishes maximum workload limits, the laboratory director is obligated to establish individual workloads, as indicated in the checklist (CYP.08575). These total limits apply regardless of the number of laboratories in which an individual works on a given day. The inspector should review the documented workload policy to ensure the workload is reassessed at least every six months for individuals who screen slides, and that the number of slides screened and the number of hours spent screening by each individual is documented daily. Specific requirements for evaluating workload are in the checklist (CYP.08500 and 08550). Workload calculations may vary with the use of automated screening instruments. Laboratories must ensure that CLIA requirements are fulfilled in addition to following workload calculations as defined in the 07/27/10 FDA Alert: How Laboratorians Can Safely Calculate Workload for FDA-Approved Semiautomated Gynecologic Cytology Screening Devices. This FDA alert provides the following calculation method, which applies to both semiautomated cytology screening systems currently on the market (Hologic’s ThinPrep® Imaging System and Becton Dickinson’s Focal Point™ Guided Screening System):

- All slides with full manual review (FMR) count as 1-slide equivalent (as mandated by CLIA for manual screening)
- All slides with field of view (FOV) only review count as 0.5- or ½-slide equivalents
- Slides with both FOV and FMR count as 1.5- or 1½-slide equivalents
• These values should be used to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an eight-hour day

Reports: Documented policies and procedures must be in place for issuing reports, including amended reports when indicated, for ensuring communication of findings to the submitting physician (especially critical and complex findings), and retention and retrieval of reports and slides. Reports must include a concise descriptive diagnosis, either in a format similar to a histopathology report or in standard descriptive terminology that includes a general categorization and descriptive diagnosis. The use of diagnostic classes is not recommended, as it does not reflect current understanding of neoplasia, has no comparable equivalent in diagnostic histopathology terminology, and does not provide for diagnosis of nonneoplastic conditions.

The laboratory should have a policy to educate providers of cervicovaginal specimens that the Pap test is a screening test for cervical cancer with an inherent false-negative rate. The preferred mechanism is an educational note on all Pap test reports that are negative (within normal limits) or display benign cellular changes. Other mechanisms include sending periodic educational information to providers.

A simple diagnosis of "Negative" is not an adequate descriptive diagnosis. However, a diagnosis such as, "Negative for malignancy" or "No malignant cells identified" is acceptable for nongynecologic, exfoliative cytology specimens (ie, urine, fluids, washings and brushings). When appropriate (particularly for fine-needle aspiration samples of mass lesions), the laboratory should include a statement regarding the adequacy of the specimen with a description of the limitations of the specimen when a specific diagnosis cannot be made.

The cytopathology report must clearly indicate the name and signature (either physical or electronic) of the pathologist who has reviewed the slides, when applicable. The records must indicate those who have reviewed the cytology slides. Cytotechnologists should be identifiable by name, initials, or other identifier in laboratory records. The reviewing pathologist’s name must be distinct from any other pathologists’ names (eg, the laboratory director) on the report. No pathologist or cytotechnologist reviewer’s signature or initials may be present unless the individual personally examined the slides from the case, including those cases released through automated screening instruments.

For gynecologic cases reviewed by a pathologist, and for all nongynecologic cases, the laboratory must ensure and document that the reviewing pathologist has reviewed and approved the completed report before release. In the occasional situation when the diagnosing pathologist is not available for timely review and approval of the completed report, the laboratory may have a policy and procedure for review and approval of that report by another pathologist. In that circumstance, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification must appear on the report.

Records must be retained in accordance with the requirements listed in the Laboratory General Checklist. In addition, cytopathology reports must be retained for a minimum of 10 years. Cytopathology reports may be retained in either paper or electronic format. Images of paper reports, such as microfiche or PDF files, are acceptable. If retained in electronic format alone, however, the electronic reports must include a secure electronic signature. Since a five-year "look-back" period is required when there is a newly identified high-grade abnormality in cervical
cytopathology, noncomputerized laboratories may wish to retain gynecologic cytopathology accession records for five years.

**On-site Case Review:** On-site review of actual case (slide) material and corresponding reports is an important element of the inspection process. This is NOT a comprehensive rescreening of slides or an evaluation of competency, but rather an effort to facilitate the inspector's evaluation of the laboratory's overall procedures. Although the case selection method may vary among inspectors, the following suggestions have been offered by members of the CAP Cytopathology Resource Committee and endorsed by the Commission on Laboratory Accreditation:

Cases should be selected from a variety of diagnostic categories. Time should be allotted to review at least 10-15 cases. The Inspector should choose several randomly selected negatives as well as cases from unsatisfactory, reactive, low-grade and high-grade intraepithelial lesions, atypical squamous cells (ASC), and positive for malignancy categories, as well as cases from nongynecologic sources. The following are core elements of the on-site review:

1. Slides should be evaluated for technical quality and specimen adequacy.
2. Significant cells should have been identified.
3. Slides should be compared with the diagnostic report for completeness and clarity of diagnostic terminology.
4. The information provided with the requisition and included in the diagnostic report should be complete and appropriate.

If, during the on-site review, there is believed to be a significant diagnostic discrepancy, this should be discussed by the pathologist team leader with the laboratory director.

Interpretations may be considered discrepant if they are not in the same series of the diagnostic menu of the CAP PAP program (eg, "100 series" versus "200 series"), or comparable major diagnostic classifications in an approved non-CAP program. Cases considered "ASC/AGC" (either by the inspector or the laboratory undergoing inspection) should not be included in the analysis to determine significant discrepancies because of the current lack of interlaboratory reproducibility of these interpretations.

**Instrumentation:** With the increasing use of automated instruments in the cytology laboratory, it is important that inspectors review the implementation, training, and procedures for these instruments. Before analyzing patient specimens, the laboratory must validate and document the functioning of the instrument in its own specific laboratory environment, including the capability of the instrument to replace existing procedure(s), if applicable. If the manufacturer does not provide validation and instrument monitoring recommendations, the laboratory must document the specific validation procedure used.

The laboratory must document the appropriate technical and interpretive training for each instrument used. Instrument performance should be routinely verified and monitored, with documented corrective actions and procedures for handling cases during instrument failure. Ongoing monitoring of instrument function and maintenance records on all devices must be documented. Monitoring of device operation must be in accordance with manufacturers’ instructions. If the manufacturer does not provide monitoring recommendations, the laboratory
must document the specific monitoring procedures used. Limits of acceptable variation must be defined in laboratory procedures.

A sample of slides from slide preparation instruments, including those using liquid-based technology and cytocentrifuge or filtration methods, should be routinely reviewed microscopically for technical acceptability.

**Safety:** Safety requirements emphasize the adequacy of ventilation in areas of specimen handling and processing and the handling of infectious tissues and other contaminated materials. The inspector should review relevant requirements from the Safety section of the Laboratory General Checklist to assure that the cytopathology laboratory is in compliance.

The laboratory must perform an initial formaldehyde monitoring procedure in all areas where this reagent is used and when exposure levels are most likely to be high (for instance, when changing reagents in the tissue processor, or when discarding specimens) and must include both the eight-hour time-weighted exposure and the 15-minute short term average exposure. Further periodic formaldehyde monitoring is mandated if results of the initial monitoring equal or exceed 0.5 ppm (eight-hour time-weighted exposure, the “action level”) or 2.0 ppm (15-minute exposure, STEL). The laboratory may discontinue periodic formaldehyde monitoring if results from two consecutive sampling periods taken at least seven days apart show that employee exposure is below both the action level and the short term exposure limit, and (1) no change has occurred in production, equipment, process, or personnel or control measures that may result in new or additional exposure to formaldehyde, and (2) there have been no reports of conditions that may be associated with formaldehyde exposure.

Xylene vapors must be monitored initially, but there is no requirement for periodic monitoring of xylene unless any personnel report signs or symptoms indicating potential exposure to fumes.

**Quality Management:** The facility’s QM program should address the validation of both normal and abnormal diagnoses and the assessment of laboratory and personnel performance. Quality measures for abnormal findings should include such activities as peer and hierarchic review, correlation of cytologic findings with histologic and clinical findings, documented evaluation of significant discrepancies, and appropriate use of intradepartmental and extra-departmental consultation.

Evaluation of the quality of negative findings is more difficult, but is very important in reducing the likelihood of a false-negative report. Routine evaluation of specimen adequacy is essential to ensure that diagnostic interpretations are not reported on unsatisfactory specimens. Among other useful techniques are retrospective review of previous material whenever a new significant abnormality is identified, and prospective rescreening of negative cases. An individual qualified to be a cytology supervisor must prospectively rescreen at least 10% of gynecologic cases screened as negative by each cytotechnologist. Rescreened slides must include both randomly selected and high-risk cases. Rescreening of random negative specimens enables monitoring of false-negative fractions, whereas rescreening of specimens from “high-risk” patients is more likely to identify abnormalities. The documented rescreening program must include negative gynecological smears received within five years of a new high-grade intraepithelial lesion or cancer diagnosis, if applicable.
The inspector should assess the procedures for rescreening and hierarchic review, including criteria for case selection (eg, identification of "high-risk" and retrospective review specimens) and provision of feedback to the original screener. The statistical records for gynecologic and nongynecologic specimens should be reviewed; benchmark data from CAP interlaboratory comparison programs are useful in evaluating the laboratory's statistical results.

The CAP has identified the use of quality indicator monitoring as a means to collect data on key laboratory quality and patient care indicators. This new process is meant to assist gynecologic cytology laboratories achieve the goal of improving laboratory quality and patient safety and maintain continuous compliance with regulatory requirements. Please refer to the FAQs concerning gynecologic cytology metrics for CAP accreditation on the CAP website at cap.org.

All quality surveillance activities should be documented, with evidence of review and evaluation. Findings should be shared with the responsible pathologists and cytotechnologists. Results should be incorporated into revisions of policies, procedures, and personnel assignments, and workload.

Practical suggestions for implementing and documenting these and other measures can be found in the CAP's Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005.

Flow Cytometry (FLO)

*Inspection of flow cytometry is not limited to the contents of the Flow Cytometry Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*

*Inspector Qualifications:* The flow cytometry inspector must have the experience and qualifications applicable to the flow cytometry services being inspected. Be aware that an inspector who has experience in blood lymphocyte subset enumeration only, may not be the best choice for a laboratory performing CD34 stem cell enumeration or DNA content and cell cycle analysis. A list of flow cytometry specialty inspectors is provided to the inspection team leader in the Inspector’s Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP inspector database specialist at 800-323-4040 ext. 7380, for the names of additional qualified inspectors.

This checklist includes blood lymphocyte subset enumeration, CD34 stem cell enumeration, leukemia and lymphoma, and DNA content and cell cycle analysis. Reticulocyte quantification by flow cytometry is covered in the Hematology and Coagulation Checklist.

The laboratory must document the optical alignment and instrument sensitivity, and run fluorochrome standards, (eg, fluorescent beads) daily. All reagents must be used within the manufacturer’s stated expiration date. The source (type) of positive controls and their frequency of evaluation will vary with the particular flow cytometry application. Control materials should consist of external positive controls for lymphocyte subsets, and CD34 stem cell enumeration.
and leukemia/lymphoma samples. In some leukemia/lymphoma situations, internal controls are acceptable. Such internal controls are the variable number of residual normal cells in the patient’s sample that may be determined by selective gating of known positive and negative populations. When antigen positive controls are not readily available through commercial controls or patient materials, then the laboratory director must implement an equivalent procedure to meet the positive control requirements (i.e., CD1a, CD103, etc.). Cryo-preserved positive patient samples or cell lines may be useful.

**Hematology and Coagulation (HEM)**

*Inspection of hematology and coagulation is not limited to the contents of the Hematology and Coagulation Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*

**Automated Blood Cell Counting:** The laboratory must have a documented, detailed procedure for calibration of automated complete blood count (CBC) instruments, including indications from the quality control system of when recalibration is needed. Calibration techniques may include the use of stabilized commercial preparations or fresh whole blood specimens. If nonadjustable, precalibrated instruments are used, the inspector must verify calibration with appropriate control materials.

Daily quality control procedures may include any combination of the following three approaches. Acceptable limits must be defined.

1. **Processing of stabilized commercial control materials:** Two different concentrations (preferably normal and high) are required for each 24 hours of patient testing. The laboratory should plot standard Levy-Jennings graphs with control limits and apply at least some Westgard multirule criteria for determining if results are analytically acceptable. It is important for the laboratory to determine its own in-house QC acceptance ranges based on its instrument's between-day imprecision rather than just utilizing the package insert values for the expected recovery range. There is no requirement for three control levels, and the use of dilute low particle concentration controls is discouraged.

2. **Retained patient specimens:** While traditionally applied to CBC instruments, this approach is only valid if there are defined limits of numeric agreement for each parameter between successive samplings and when used in conjunction with stabilized QC materials.

3. **Moving average algorithm for erythrocyte indices and other parameters:** The laboratory should set limits that are sensitive to significant alterations in calibration status, yet insensitive to minor fluctuations in patient population values.

Fluids used with CBC instruments must be periodically checked for contamination. Suggested checks include instrument background counts. Since nucleated erythrocytes and blood megakaryocytes may have an additive effect on the instrument leukocyte count, appropriate count correction procedures must be present for these constituents. There also must be
protocols for common interferences that may affect the accuracy of CBC data, such as lipemia, in-vitro hemolysis, microclots, cold agglutinins, and rouleaux. Patient results that exceed laboratory defined reportable limits must be verified (eg, cytopenic samples should be checked against hemocytometry or blood film estimates) prior to reporting.

**Automated Differential Counters**: Such instruments must be carefully evaluated against previous patient-testing methods before being placed in service. Quality control options include periodic comparisons with manual differentials or processing of commercial control materials with at least two different classes of leukocytes or WBC surrogates. The commercial quality control material should contain surrogate subtype particles that are enumerated by the instrument and reported by the laboratory. The laboratory must have criteria for checking and reviewing leukocyte differential counter data, histograms, and/or blood smears, which have clinically important results flagged by the automated counter.

**Manual Blood Films**: There must be documented criteria for review of blood films with specified abnormalities by the pathologist, supervisor, or other technologist qualified in hematomorphology. The laboratory must have a system that ensures that all personnel report microscopic morphology in a similar fashion. Suggested methods to accomplish this include:

- Circulation of blood films with defined leukocyte differential distributions and specific qualitative abnormalities of each class of cells, and/or
- Multihedral microscopy, and/or
- Use of blood or bone marrow photomicrographs with referee and consensus identifications, such as those from previous CAP Surveys
- Digital images

**Automated Reticulocytes**: The laboratory must have precision data for its automated method, based on analysis of commercial controls or comparison with manual methods. Documented criteria must be present for identifying samples that may give erroneous results due to interferences (eg, Howell-Jolly bodies, nucleated RBC, basophilic stippling, macrothrombocytes). For flow cytometry systems not using commercial kits approved by the FDA, there must be evidence of evaluation of the strength and stability of the fluorescent dye binding to RNA or DNA-RNA.

**Manual Reticulocytes**: To reduce the imprecision of microscopic enumeration, the reported reticulocyte concentration must be based on a minimum sample size of 1,000 red cells. When using a Miller disc a minimum of 112 cells must be counted. The fields from which the count is taken must contain at least 1,000 red cells.

**Bone Marrow Preparations**: The inspector must review bone marrow slides (routine and cytochemical stains) to assess technical adequacy. If fixed tissue sections and aspirates are independently evaluated by different sections of the laboratory, there must be a mechanism to compare data and interpretations before reports are released by pathologists or qualified hematologists.

**Abnormal Hemoglobin Detection**: If the laboratory uses alkaline cellulose acetate or isoelectric focusing as a separation technique, all abnormal bands must be verified by solubility testing, acid agar electrophoresis, and/or HPLC, as appropriate. In the absence of a primary screening method, solubility ("sickle") testing alone is not sufficient for detecting or confirming
the presence of sickling hemoglobins, and the laboratory must recommend further confirmatory testing.

**Body Fluids:** The procedure manual must address handling of partially clotted specimens, cell clumps, or debris noted during hemocytometry or automated counting. For instrument counts, the laboratory must have documentation of linearity studies and defined limits beyond which instrument counts are not reliable. Differentials should always be performed on stained preparations, and use of the cytocentrifuge is strongly recommended. As with blood film morphology, there must be a system to ensure consistency of morphologic classification when multiple personnel are responsible for smear examination. A pathologist or other qualified physician must review body fluid preparations that contain suspected malignant cells.

**Semen Analysis:** This section covers basic semen testing. In addition to the checklist items addressing body fluid cell counts, there is an emphasis on issues of specimen collection, motility assessment, and stained morphology classification. More specialized requirements are found in the Reproductive Laboratory Checklist, which is used only for laboratories that participate in the Reproductive Laboratory Accreditation Program.

**Coagulation Tests:** Laboratories serving acute care hospitals must be able to perform a sufficient variety of coagulation tests to evaluate common coagulation disorders. Such tests typically include platelet concentration, prothrombin time, activated partial thromboplastin time, fibrinogen assay, fibrin(ogen) degradation products or D-dimer, and platelet function tests such as bleeding time or whole blood in vitro platelet function.

The laboratory must collect all coagulation specimens into 3.2% buffered sodium citrate, and it must document guidelines for rejection of under- or overfilled collection tubes.

The laboratory must report patient results with the accompanying reference ranges. Appropriate controls (at least two levels) must be performed for all procedures for each eight hours of patient testing.

For prothrombin time, the laboratory must have documentation that the International Sensitivity Index (ISI) is appropriate to the particular prothrombin time reagent and instrumentation used. The ISI value may change with each new lot of prothrombin time reagent. The International Normalized Ratio(s) (INR) values are often used to monitor patient therapy with oral anticoagulant medications. It is critical to calculate and report appropriate INR values, which must be appropriately adjusted for every new lot of prothrombin time reagent, changes in types of reagent, or changes in instrumentation. The appropriate mean of the prothrombin time reference interval must be used in the INR calculation. The laboratory must check patient reports at least once per year for correct INR calculations, patient values, and reference intervals.

With improvements in the precision of semiautomated and automated coagulation instruments as well as more uniform commercial reagents, single test determinations are acceptable if the laboratory meets appropriate quality standards. Single test results should be statistically indistinguishable from duplicate test results.

Plasma-mixing studies (ie, mixing patient plasma with normal plasma) may be performed to distinguish whether a factor deficiency or an inhibitor causes an abnormal coagulation screening
test result (prothrombin time or aPTT). When mixing studies are performed, the normality of the “normal” plasma must be verified. In general, pooled plasmas prepared in the laboratory or commercial products that include all coagulation factors are acceptable.

The laboratory must have a procedure to detect heparin or other antithrombotic drugs that inhibit coagulation in patient samples. Platelet aggregation studies must be performed at 37 degrees Celsius, and blood specimens for initial platelet function studies and platelet aggregation must be handled at room temperature before testing.

If factor assays are performed, the inspector should examine sample assay data to determine that appropriate calibration points and two dilutions of patient plasma are routinely used.

**Waived Test Requirements**: Certain checklist requirements are now different for waived tests versus nonwaived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 42).

**Histocompatibility (HSC)**

*Inspection of histocompatibility is not limited to the contents of the Histocompatibility Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*

The Histocompatibility Checklist is for laboratories performing HLA testing by serologic, molecular, or flow cytometry or other solid phase antibody identification methods.

*Inspector Qualifications*: Inspectors of a histocompatibility laboratory must be pathologists, clinical scientists, or medical technologists who are actively involved with or have extensive experience in the practice of histocompatibility testing and are knowledgeable about current CAP checklist and corresponding CLIA requirements. CAP histocompatibility inspectors should have the qualifications for technical supervisors of a CAP-accredited histocompatibility laboratory or have experience in a supervisor position and at least five years experience in clinical histocompatibility. The inspector should have experience in a laboratory similar in size and scope of work to the laboratory being inspected. Major areas that define the scope of work include:

**Clinical**
- Stem cell (progenitor cell) transplantation using related donors only
- Stem cell (progenitor cell) transplantation using unrelated donors
- Renal transplantation—deceased donors
- Renal transplantation—living donors
- Other Solid Organ transplantation – deceased donors
- Non-transplantation clinical purposes (platelet transfusion, disease risk assessment, etc)
- Relationship testing

**Technical**
A list of histocompatibility specialty inspectors is provided to the inspection team leader in the Inspector’s Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP inspector database specialist at 800-323-4040 ext. 7380 for the names of additional qualified inspectors. If the team leader has a potential inspector that meets the defined qualifications who is not on the specialty list, the inspector can submit his or her qualifications to be evaluated for addition to the specialty list by contacting the LAP inspector database specialist.

**Before the Inspection:** The Inspector’s Inspection Packet contains information about the laboratory’s scope of histocompatibility activities and personnel qualifications. The inspector should thoroughly review these materials, along with the Histocompatibility Checklist. If an inspector determines that the scope of the laboratory is such that he or she does not feel qualified to inspect it, the team leader should be contacted immediately. CAP staff can assist the team leader in locating additional histocompatibility inspectors if needed.

Allow sufficient time for the inspection. Laboratories performing stem cell and multiple organ transplants usually require one full day for an inspection.

The types of tests the laboratory performs and the clinical programs it supports will guide the evaluation of personnel qualifications and continuing education activities.

Some of the Histocompatibility Checklist items have notes following the requirements. These notes contain additional information to enhance the understanding of the intent of the checklist item within the context of the laboratory being inspected.

**During the Inspection:** The inspector must address all checklist requirements. Be thorough but efficient, completing the inspection in a reasonable period of time.

**Quality Control and Proficiency Testing:** The inspector should review proficiency testing results and QC for all tests performed in detail with emphasis on documentation of corrective action. It is important that the inspector verify that the laboratory participates in proficiency testing programs accepted by the College’s Commission on Laboratory Accreditation.

**Leadership:** Policies and procedures should clearly explain how the laboratory leadership addresses the following issues: testing quality; level of testing according to clinical need; repeat testing; and which technique to use in specific cases when more than one technique is available. The inspector should evaluate the degree of involvement of the supervisor and director.

**Reports:** Reports vary considerably among histocompatibility labs, and the inspector should review a sampling for correct use of nomenclature, accurate description of the tests performed, and meaningful final interpretation of the results.
**Personnel:** Evaluation of the expertise and training of personnel must take into account the tests performed and the transplant programs the laboratory supports. The inspector must determine if the policies to assess personnel competency are appropriate. There must be documented evidence of sufficient continuing education credits for directors, supervisors, and other technical personnel. The technical supervisor (section director) must have a MD, DO, or PhD in biological or clinical laboratory science, and either four years training and experience in histocompatibility, or two years and experience in general immunology plus two years in histocompatibility.

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

**Immunology (IMM)**

*Inspection of immunology is not limited to the contents of the Immunology Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*

The laboratory must check new kits and reagents against old lots to ensure comparable reactivity before or concurrently with being placed in service. For qualitative tests, minimum crosschecking includes retesting at least one known positive and one known negative sample from the old reagent lot against the new reagent lot, ensuring that the same results are obtained with the new lot. Good clinical laboratory science includes patient-based comparisons in many situations, since it is patient results that are "controlled."

For qualitative tests, the laboratory must run and document positive and negative controls at least once each day of analysis, based on the manufacturer's recommendations. For quantitative tests, control samples at more than one level must be run at least once each day of analysis. When results are reported as "weakly" positive, the laboratory must use a weakly positive control.

Certain immunologic reagent/kit systems include internal positive and negative controls. If so, external matrix-appropriate controls are required with each new lot number or new shipment of a lot number or every 30 days, whichever is more frequent. At a minimum, manufacturers' recommendations must be followed. For panels or batteries, controls must be employed for each analyte sought in patient specimens. If internal positive and negative controls are NOT present, a positive and negative control must be tested each day of analysis for all qualitative or semiquantitative antigen/antibody tests. The checklist provides clarification of when controls must be evaluated.
Microbiology (MIC)

Inspection of microbiology is not limited to the contents of the Microbiology Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.

The Microbiology Checklist is divided into six subsections: (1) bacteriology, (2) mycobacteriology, (3) mycology, (4) parasitology, (5) virology, and (6) molecular microbiology, as well as an initial general section applicable to all subspecialties. Judgment is required on the part of the inspector to determine whether the level of service is appropriate to the institution's needs. Laboratories serving larger institutions will likely provide all services for the subsections listed above. Smaller laboratories may still meet the Standards of Laboratory Accreditation by providing reliable preliminary screening and/or identification and then referring specimens or cultures for more definitive analysis to a reference laboratory when necessary for patient management.

Quality Control: This section includes QC requirements for prepared and purchased culture media, staining procedures, reagents, antimicrobial susceptibility tests, instruments, and equipment. For each procedure, medium, reagent, and item of equipment to be monitored, the laboratory should define control methods, as well as the frequency of testing, limits for acceptability, and action to be taken when not acceptable.

Media: The inspector should review the following in regards to culture media:

• The laboratory must ensure that all media used, whether purchased or prepared in-house by the laboratory, are sterile, are able to support growth appropriately, and are appropriately reactive biochemically.
• For laboratories preparing their own media, it will be necessary to maintain stock or reference organisms and to test the media before, or concurrently, with use. Explicit documentation of such testing is essential and must be retained for at least two years.
• For prepared, purchased media, the laboratory must have explicit documentation that each lot is tested for ability to support growth of appropriate organisms and biochemical reactivity at the time of receipt or concurrent with use in the laboratory. The user must control the media for reactions that are not tested by the preparer (e.g., proper function of sheep blood agar for the CAMP test).
• Laboratories that rely on manufacturers' QC of media must have a copy of the CLSI document M-22-A3, Quality Assurance for Commercially Prepared Microbiological Culture Media. The manufacturer or preparer must supply documentation to the user that its QC activities meet the CLSI guidelines. For each lot, the preparer must certify that QC performance was acceptable and that a record of the lot numbers for all media is retained for at least two years. The user laboratory may record this information in place of the more detailed documentation of media performance.
• The end user must document that each shipment has been visually examined upon receipt for breakage, contamination, appearance, or evidence of freezing or overheating upon receipt.
• For media not listed specifically in M-22-A3 as being exempt from such testing, the user must continue to test each lot for ability to support growth, and appropriate biochemical reactions using QC methods employed for media manufactured in-house.
• Identification and susceptibility quality control: The director is responsible for the quality and performance of media and all media failures and the resultant corrective action taken must be documented.
• The laboratory must test each shipment or lot of a commercial identification system for appropriate performance. If a laboratory qualifies, they may perform streamlined quality control as defined in CLSI M-50.
• The laboratory can accomplish QC of antimicrobial susceptibility tests by monitoring the performance of the test system with appropriate reference control organisms. Control organisms must be run with each new lot or batch of antimicrobials or media, and daily thereafter. The QC frequency may be reduced from daily to weekly once satisfactory daily performance for 20 consecutive days (with no more than one result out of range) or 30 consecutive days with no more than three results out of range) is documented. Whenever weekly tests yield unacceptable results, daily QC testing must be performed until the cause of the unacceptable results is determined and resolution of the problem is documented. Before returning to a weekly QC frequency, the laboratory must document five consecutive days of satisfactory quality control results.

Stains:
• Gram stain – The laboratory must perform quality control with each batch at least weekly.
• Non-Immunofluorescent stain (other than gram stains) – The laboratory must perform quality control with each new batch, lot number and shipment.
• Fluorescent Stains – The laboratory must perform quality control each time of use.
• The director is responsible for developing and implementing a system to ensure consistency among all personnel that perform and interpret Gram and other organism stains.

**Bacteriology:** The inspector’s discretion is necessary to evaluate a laboratory’s protocols for specimen work-up and identification of organisms and test systems. For example, no specific requirements are listed for the extent of work-up of specimens such as sputum, urine, stools, and wounds. Policies should be mutually acceptable to the medical staff and the laboratory. Selection of antibiotics to be tested and reported with each antimicrobial susceptibility test requires input from the pharmacy department and the medical staff. For hospital-based microbiology laboratories, the laboratory should maintain and report cumulative antimicrobial susceptibility test data to the medical staff at least yearly.

The inspector should assess the adequacy of the blood culture system for detection of microorganisms for the patient population. It is recommended that the laboratory keep blood culture statistics as a monitor of collection techniques, including the number of true positive cultures and the number of contaminated culture.

**Waived Test Requirements:** Certain checklist requirements are now different for waived tests versus nonwaived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 42).
**Mycobacteriology:** The CAP supports a policy that encourages laboratories to use the most rapid and reliable methods available for detection and identification of mycobacteria, especially *M. tuberculosis*. This is of particular importance in areas where the incidence of tuberculosis is increasing. Requirements relating to smears, processing, culture media, identification, and susceptibility testing of mycobacteria are contained in the checklist. The laboratory must use fluorochrome stains for microscopic examination of slides prepared from primary patient specimens. The inspector must assess the relevancy of these requirements in relation to the incidence of tuberculosis in the geographic area or patient population served.

**Mycology:** All staining procedures must be checked and results recorded for each new batch of preparations, and at least daily against known positive and negative control organisms. If fluorescent stains are in use, quality control must be performed each time of use. For stains such as Gomori methenamine silver and Giemsa, the slide itself serves as the negative control. Controls for KOH preparations are not required.

**Virology:** The laboratory must have the appropriate minimal cell lines available for all of the virology testing performed in the laboratory; a listing of recommended cell lines appears in the checklist. Continuous cell lines must be checked for *Mycoplasma* and endogenous contamination. The laboratory must have established criteria for the acceptance and rejection of cell culture media (tubes, vials, flasks, trays) used for virus isolation. Media must be checked for sterility if additives are added after initial sterilization. Removal of aliquots for refeeding does not require additional testing for sterility.

**Parasitology:** The laboratory must perform concentration procedures and permanent stained preparations on all stools submitted for parasitological microscopic examination. A microscopic examination of liquid stools should include a direct wet mount if submitted fresh. Laboratories must have an ocular micrometer available for determining the size of eggs and larvae, and the laboratory must calibrate the micrometer for the microscope in which it is used. The micrometer does not require periodic checking if the optical path is unaltered. Examination of peripheral blood films for blood parasites must include preparation and examination of a thick film as well as a thin film for increased sensitivity. For blood films positive for malaria parasites, the report must include the percentage parasitemia. The inspector should ensure that the laboratory has fulfilled requirements for formaldehyde testing (MIC.53050).

**Molecular Microbiology:** This section is applicable to any infectious disease molecular testing. There are subsections for general requirements, FDA-cleared nonamplification methods, FDA-cleared amplification methods, and laboratory-developed or modified FDA-cleared tests. See the next section for additional information on inspecting molecular testing. The inspector of molecular microbiology must be actively practicing in this area, but the individual need not be on the CAP list of molecular pathology inspectors.
Molecular Pathology (MOL)

Inspection of molecular pathology is not limited to the contents of the Molecular Pathology Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.

Checklist Usage: The Molecular Pathology Checklist is used for the inspection of laboratories performing clinical molecular genetic testing, including, but not limited to, oncology, hematology, inherited disease, pharmacogenomics, HLA typing, forensics, and parentage applications.

Inspector Requirements: Inspection of a molecular genetics laboratory requires special knowledge of the science. Molecular pathology inspectors should be actively practicing molecular scientists familiar with the checklist and possessing the technical and interpretive skills necessary to evaluate the quality of the laboratory’s performance. A list of molecular pathology specialty inspectors is provided to the inspection team leader in the Inspector’s Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP inspector database specialist at 800-323-4040 ext. 7380 for the names of additional qualified inspectors.

Preparing to Inspect: The inspector must be familiar with the Molecular Pathology Checklist, and should review the checklist prior to the inspection along with the Laboratory General and the All Common Checklists. If the intent of any checklist requirement is not clear, the CAP’s technical staff can offer further explanation or interpretation at 800-323-4040 ext. 6065. The inspector must review the laboratory’s activity menu and instrumentation lists in order to understand the type and scope of testing the laboratory is performing.

Inspection Process: The inspector will verify that procedures are designed to minimize carryover and cross-contamination through use of appropriate physical containment and procedural controls. There must be adequate physical separation of pre- and post-amplification areas to avoid amplicon contamination. Laboratory personnel must change gloves frequently during processing and must use dedicated pre- and post-pipettes (positive displacement or with aerosol barrier tips). The laboratory must run internal controls to detect a false negative reaction secondary to extraction failure or the presence of an inhibitor, when appropriate.

Assay Validation: The inspector will ensure that prior to clinical implementation of a new assay the laboratory has established an appropriate process of test validation and documented its implementation. Validation requires identifying the needs of the user and establishing documented evidence that provides a high degree of assurance that a test will consistently meet those needs. For FDA-approved tests, the manufacturer must define the needs of the user (intended use and clinical utility) and establish the performance characteristics. Therefore, validation of FDA-approved tests only requires verification of the analytical performance characteristics of accuracy, precision, reference range, and reportable range. However, if an FDA-approved test is modified to meet the needs of the user or the test is developed by the laboratory (LDT), then the laboratory must establish both analytical and clinical performance parameters. Analytical performance parameters include accuracy, precision, reference range,
reportable range as well as analytical sensitivity, analytical specificity, and any other parameter that is considered important to ensure the analytical performance of the test (eg, specimen stability, reagent stability, linearity, carryover, cross-contamination, etc). Clinical performance characteristics include clinical sensitivity, clinical specificity, positive and negative predictive values, and clinical utility. Prior to reporting patient results the laboratory director (or designee who meet CAP director qualifications) must sign a summary statement documenting the review of the validation studies and approval of the test for clinical use.

Please refer to two articles: “Test Verification and Validation for Molecular Diagnostic Assays” (Arch Pathol Lab Med. 2012;136: 11-52), which is available at cap.org “Recommended Principles and Practices for Validating Clinical Molecular Pathology Tests” (Arch Pathol Lab Med. 2009;133[5]: 743–755), which is available at cap.org.

**Result Reporting:** The inspector will verify that the final report is reviewed and signed by the director or a qualified designee if there is a subjective or an interpretive component to the test. When appropriate, the report may include a recommendation for genetic counseling to explain the implications of the test result. For assays performed on histology/cytology specimens, the interpretive report must include correlation with morphologic findings, as applicable. The inspector should verify that for ASRs, federal regulations require that the following disclaimer accompany the test result on the patient report: “This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the US Food and Drug Administration. The CAP recommends additional language, such as, … The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical laboratory testing.

Please refer to the article “Clinical Laboratory Reports in Molecular Pathology” (Arch Pathol Lab Med. 2007;131[6]:852–863) which is available at cap.org.

**Quality Management:** The laboratory must investigate its failed runs and suboptimal analyses for improvement opportunities. The inspector should ask for the record of such events. There must be documentation that each failure is investigated for cause.

**HER2:** The inspector should be aware that the inspection checklist contains requirements from the ASCO/CAP guidelines for HER2 relating to validation of HER2 assays, fixation of specimens, and reporting of results with ASCO/CAP scoring criteria. The ASCO/CAP guidelines may be found at cap.org and may be periodically revised.

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

*Inspection of the point-of-care testing areas is not limited to the contents of the Point-of-Care Testing Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*
Point-of-care testing (POCT) is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space and that are performed outside the physical facilities of the clinical laboratories. Examples include kits and instruments that are hand carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g., capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (e.g., operating room, intensive care unit). POCT does NOT include limited service satellite laboratories with fixed dedicated testing space; these are covered under the Limited Service Laboratory Checklist.

CLIA classifies tests according to complexity into waived and nonwaived categories. The nonwaived category is further subdivided into tests of moderate and high complexity.

This checklist covers only tests that are classified as waived or moderately complex (provider-performed microscopy [PPM] is a subset of moderately complex tests). In the current edition of the checklist, requirements for quality control, reagents, and calibration are different for waived tests, as compared to moderately complex tests; please refer to the relevant individual POC Checklist sections for further details. Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and moderately complex tests. The current list of tests waived under CLIA may be found at accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm.

**Waived Test Requirements:** Certain checklist requirements are now different for waived tests versus nonwaived tests. Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and nonwaived tests. Refer to the Requirements Common to All Laboratory Sections section.

Tests/instruments that are NOT covered by the POC Checklist include all tests classified under CLIA as high complexity, as well as legal drug testing, multichannel blood cell counters, bacterial cultures, and tests that use instruments requiring high levels of maintenance or technical skill. CAP headquarters may be contacted for information about whether a specific test or instrument may be inspected using the POC Checklist. Contact the CAP through the accreditation email site (accred@cap.org), or call 800-323-4040.

If a POCT site has a scope of service in a particular laboratory discipline that exceeds those addressed in this checklist, then a section-specific checklist (e.g., hematology, microbiology) may be required. Blood gas testing requirements have been added as a new section to the POCT Checklist, and these should be used to inspect blood gases done at the point of care or near patient testing.

The POC Checklist does not cover patient self-testing. The CAP Laboratory Accreditation Program does not inspect or accredit patient self-testing.

To be accredited, all analytes being measured under the POCT program/site must be included in the on-site inspection. POCT programs may be inspected as sections of the central laboratory if they are registered under the same CLIA number. In this circumstance, they are included in the Laboratory General and Team Leader Checklists used for the central laboratory. If the
POCT sites are registered under separate CLIA numbers, separate Laboratory General and Team Leader Checklists must be completed for each POCT program. The POCT program may be centrally coordinated, with designated qualified personnel who review testing procedures and quality control and who conduct training of the testing personnel, although this is not a requirement.

When records are maintained centrally by a designated coordinator or POCT director, only one copy of the Point-of-Care Testing Checklist need be completed. The inspector will review all centrally maintained records and visit at least a sampling of the testing sites in order to evaluate compliance with the standards. Therefore, the POCT locations must be identified in the application/reapplication process. If records are not maintained centrally, the inspector must visit each POCT site, and a separate checklist must be completed for each location. In the latter case, each POCT site will be inspected as an additional laboratory section.

Each person performing POCT must maintain satisfactory levels of competence. Competency must be assessed following training but before the person performs patient testing. Thereafter, during the first year of an individual’s duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually. The Personnel section of the POC Checklist indicates six elements of competence. All of the elements that are applicable to an individual's duties must be evaluated for individuals who perform nonwaived testing. For waived testing, it is not necessary to assess all six elements at each assessment event. The POCT program may select which elements to assess. If the competency of physicians and midlevel practitioners is established and monitored by the credentialing process of the institutional medical staff, then this section is not applicable to them.

All point-of-care testers who are performing nonwaived testing must be included on the Laboratory Personnel Roster, which is submitted to the CAP at the time of reapplication. The inspector will review personnel records for a selection of these testers for diplomas, transcripts, or licenses qualifying them to perform testing per CLIA requirements.

The College of American Pathologists defines provider-performed testing (PPT) as testing that is personally performed by a physician in conjunction with the physical examination or treatment of a patient and is limited to the 13 tests mentioned in this section. Patient management is often facilitated by immediate and direct physician performance of certain laboratory tests at the time of a patient encounter. Although these tests may be simple to perform, standards must be maintained to ensure correct results. The other sections of the Point-of-Care Testing Checklist do NOT apply to PPT.

This section is applicable only if both of the following conditions are true:

1. PPT is performed under the same CLIA number as the laboratory, and
2. The laboratory director is responsible for competency assessment of the physicians and midlevel practitioners.

This section is not applicable if both of the following conditions are true:

1. PPT is performed under the same CLIA number as the laboratory, and
2. The institutional medical staff has established the competency of physicians and midlevel practitioners through credentialing process.

This section is not applicable if PPT is performed under a different CLIA number than the laboratory, regardless of how physician and midlevel practitioner competency is established.

The PPT category is not the same as the US CLIA term “provider performed microscopy” (PPM), which allows non-physicians to perform certain tests. Rather, PPT includes both waived tests under CLIA and PPM, but only when a licensed physician performs them. PPT is currently limited to the following tests:

1. pH, body fluids
2. Vaginal pool fluid smears for ferning
3. Fecal leukocytes
4. Gastric biopsy urease
5. Nasal smears for eosinophils
6. Occult blood, fecal and gastric
7. Pinworm examination
8. Post-coital mucus examination
9. Potassium hydroxide (KOH) preparations
10. Semen analysis, qualitative
11. Urine dipstick*
12. Urine sediment microscopy
13. Wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements

Team Leader Assessment of Director & Quality Checklist

(This checklist does not apply to the Biorepository Program.)

This checklist evaluates the qualifications of the laboratory director and the effectiveness of the director in implementing the standards of the CAP’s laboratory accreditation programs, including the laboratory’s quality management plan. The team leader or team member who is qualified and trained to be a team leader must complete this checklist. During the inspection, the following key activities are needed to complete the requirements in the Team Leader Assessment of Director & Quality Checklist:

1. Interview with the laboratory director
2. Interviews with laboratory personnel as appropriate
3. Observation of the operation of the laboratory
4. Review of the laboratory organizational chart, quality management plan and records, committee minutes, and other relevant documents
5. Interview with the hospital administrator (If the laboratory is an independent organization, an executive from the organization should be interviewed.)
6. Interview with the chief of the medical staff or designated medical staff leader (for laboratories associated with a medical staff)
Interviews are best scheduled in the afternoon, after the team leader has had an opportunity to gain an impression of laboratory conditions. Other members of the team will perform some of the activities identified above so the team leader should check with them during lunchtime in order to be better prepared. At least 15–20 minutes should be allowed for each interview. Open-ended questions are usually best. For instance, “Tell me about how the annual quality management plan is put together?” will be much more revealing than, “Do you review the quality management plan each year?” Discussion of the laboratory’s financial and/or contractual arrangements is prohibited.

The laboratory director’s curriculum vitae is included in the inspection packet, and it should be reviewed prior to the inspection. The team leader should meet briefly with the laboratory director at the beginning of the inspection if possible, in order to review the goals of the inspection, review any perceived problems in the laboratory, and reserve the team leader checklist to use for a second interview later in the day. Key aspects of the later interview are to determine the laboratory director’s familiarity with and involvement in critical laboratory operations, particularly as regards to quality management, as well as to whether the director has sufficient responsibility and authority to operate the laboratory and to ensure the implementation of a safe laboratory environment. If the inspection reveals systemic problems, appropriate deficiencies from the Team Leader Checklist should be cited. The interview with the director is also an opportunity to review problem areas (e.g., space, staffing) that the inspection experience might serve to resolve.

If some of the laboratory director’s activities are delegated to others, there must be documentation of which qualified individuals are authorized to act on his/her behalf for specific activities, and there must be documentation that the laboratory director has ensured that these activities have been carried out appropriately. If the laboratory director is not present full-time at the laboratory, documentation of the frequency of visits and the activities of the director during visits must be verified.

The meeting with the CEO or other hospital administrator with responsibility for the laboratory is an opportunity to ensure that he or she understands the CAP inspection philosophy, goals, and methods, particularly the value of proficiency testing (a significant cost item), as well as to determine the administration’s perception of the laboratory service. Has the laboratory established a working relationship with the administration? An evaluation of the administration’s view of the laboratory director’s role and authority in the laboratory is essential. A discussion of any space and staffing needs that are identified during the inspection is appropriate.

The meeting with the representative of the medical staff should ascertain if the laboratory is meeting the staff’s needs for patient care, and should determine the contribution of the laboratory director (and other pathologists) to the institution’s education needs, committees, quality management, and patient safety activities. Questions directed to suggestions as to how laboratory service could be improved may be helpful.

Visit the CAP website Virtual Library of Audioconferences to hear the “Complying with the Team Leader Checklist” audioconference.

Transfusion Medicine (TRM)

Inspection of transfusion medicine is not limited to the contents of the Transfusion Medicine Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must
be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.

The Transfusion Medicine Checklist emphasizes proper procedure in specimen collection and handling, maintenance of records, monitoring of instruments and equipment, test performance, and verification and documentation of reagent performance.

**Component Accession and Disposition Records:** Component records must include documentation of each component from receipt/collection through processing, storage, and testing, to final disposition, including transfusion records.

**Technical Procedures:** Blood typing and compatibility procedures should be directly observed by the inspector to see if actual practice corresponds to the procedure manual. The laboratory must validate new test systems and reagents prior to use. The inspector should review the records for such changes during the course of the inspection.

**Blood and Blood Components:** If blood and blood components are prepared or modified, the processes should be reviewed to ensure proper product labeling to include all FDA-required information, correct assignment of expiration dates, maintenance of the sterility of the components, and appropriate quality control. The inspector should conduct a physical inspection of refrigerators, freezers, and other equipment used to store blood and blood components to verify proper storage conditions and appropriate organization within the storage units. Temperature and maintenance records, including alarm checks should be reviewed carefully for deviations and appropriate corrective actions. The checklist requirements apply to storage units within the transfusion service, and to other blood storage areas located elsewhere in the facility (eg, surgery, nursing, dialysis units, etc).

**Storage and Issue of Tissues:** The laboratory should adequately define authority and responsibility for all aspects of the tissue-handling program to ensure compliance. If the transfusion service is involved in the procurement and processing of tissue, other than blood, the laboratory’s authority and responsibilities in the program must be defined. The laboratory must maintain records to document appropriate storage conditions, as well as disposition.

**Transfusion:** The inspector should observe with particular emphasis on patient identification and blood component administration procedures. The transfusion service must positively and completely identify blood specimens taken for compatibility testing before leaving the patient’s side, and the transfusion recipient must always be identified conclusively at the bedside by either two persons or by using bedside patient identification technology. The transfusion service must actively monitor key elements of the transfusion process and have a system to reduce the risk of mistransfusion. The transfusion service must report findings of a transfusion reaction investigation in a timely and effective manner. An agreement or understanding must exist between the transfusion service and the clinical areas to ensure provision of blood, blood components, and tissue on a timely basis. Confirm that the transfusion service medical director participates in establishing criteria for transfusion and monitoring transfusion practices.

**Donor Procedures and Apheresis:** If donors are drawn and/or units are processed at the facility, the inspector should evaluate each step, including the details of the donor interview,
phlebotomy, and storage/release/quarantine procedures. If infectious disease testing is performed at the facility, the inspector should review the adequacy and appropriateness of procedures.

**Bone Marrow and/or Progenitor Cells:** This section is intended for laboratories involved in the collection, processing, storage, and reinfusion of bone marrow and/or progenitor cells. Responsibilities of all parties in the collection, transport, processing, storage and administration of cellular therapy products must be defined. If possible, the inspector should directly observe a product collection to see if actual practice corresponds to the procedure manual. The inspector should ensure that all products and reagents used in the collection are stored properly and that all documentation is accurate and complete.

**AABB Coordinated Inspections:** In some cases, a hospital transfusion service or blood bank may apply for dual accreditation by the CAP and the AABB. While compliance with the current edition of the Standards for Blood Banks and Transfusion Services of the AABB also represents good laboratory practice, accreditation by the AABB and the CAP are separate events. Therefore, if an AABB inspection is performed simultaneously with a CAP inspection, all requirements in the Transfusion Medicine Checklist, the Laboratory General Checklist, and other CAP checklists (as applicable) must be addressed to qualify for accreditation by the CAP.

**Urinalysis (URN)**

*Inspection of urinalysis is not limited to the contents of the Urinalysis Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections.*

**Specimens:** The laboratory must provide instructions for proper collection of clean voided urine specimens that avoids contamination and deterioration of constituents. It should examine specimens within one to two hours of collection unless properly preserved. Simple refrigeration may not be adequate, as it will not prevent the lytic effects of low specific gravity or alkaline pH on sediment elements and may induce crystal formation.

**Manual Tests:** The laboratory must verify refractometer calibration at least annually with at least two solutions of known specific gravity. While the definition of a "complete" urinalysis is at the discretion of the laboratory, and dependent upon the population tested, the following chemical constituents are considered important: glucose, protein, blood or hemoglobin, nitrite, and leukocyte esterase. The laboratory must document criteria for when a routine urinalysis does not require sediment microscopy. Microscopes must be clean, adequate (eg, low, high dry, and oil immersion lens), and properly maintained with documentation of preventive maintenance. Dipstick findings must be correlated with microscopy. The laboratory must have a system that ensures that all personnel report microscopy morphology in a similar fashion. Suggested methods to accomplish this include:

- Circulation of preserved urine sediments with defined abnormalities involving leukocytes, erythrocytes, bacteria, yeast, and/or
- Multiheaded microscopy, and/or
- Use of urine sediment photomicrographs with referee and consensus identifications, such as those from former CAP Surveys and/or
- Digital images
Automated/Semiautomated Tests: The laboratory should be documented criteria for identifying urine samples that may give erroneous results with a dipstick reader. It should carefully compare automated imaging systems with manual microscopy before being used for patient reporting, and cell count controls must be processed no less frequently than each day of patient testing.

Waived Test Requirements: Certain checklist requirements are now different for waived tests versus nonwaived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area, of this accreditation manual for specific detail (see page 42).

Reproductive Laboratories

Laboratories enrolled in the Reproductive Laboratory Accreditation Program (RLAP) are inspected with the Reproductive Laboratory Checklist, the Laboratory General Checklist, the Team Leader Assessment of Director & Quality Checklist, and the All Common Checklist. Other checklists may also be required, most notably the Chemistry and Toxicology Checklist in laboratories performing endocrine assays.

Laboratories in the RLAP have some unique aspects, including:

• Few reproductive laboratories are located in a hospital setting, rather are within physician suites or outpatient surgery centers. As a result, the laboratory must develop many programs typically provided by the parent institution (eg, fire and electrical safety, human resources, and equipment maintenance).
• The laboratories are staffed with fewer personnel and are dedicated to the performance of a highly select group of clinical procedures (embryology and andrology). The limited staffing requires the laboratories to have policies for providing back-up personnel to ensure patient care needs.
• Most reproductive laboratories are inspected by one person; a team is generally not required. RLAP inspectors may either participate in the on-line inspector training or in specialized inspector training courses periodically offered in conjunction with the annual ASRM meeting.
• Reproductive laboratories are not subject to unannounced inspections at this time.
• Embryology laboratories are not subject to CLIA; therefore, director requirements for embryology-only laboratories are different from laboratories and laboratories performing clinical laboratory testing, such as andrology or endocrine testing (see the appropriate section in the Reproductive Laboratory Checklist for the embryology laboratory director requirements).

Inspection Requirements:
• The inspector should observe the testing and processing of specimens submitted for semen analysis and therapeutic insemination. For therapeutic insemination specimens, review records for verifying and maintaining the identity of the specimen for all processes from receipt to final disposition.
• The inspector should observe the processing of oocytes and embryos for assisted reproductive technology procedures (ART) and cryopreservation. Check for time-out records to confirm patient identification and proper procedure to be performed prior to initiation of procedures and for appropriate culture and cryo storage conditions.
• The inspector should review a sampling of patients’ treatment cycle records for completeness and documented disposition of each gamete and embryo. For reproductive
tissues stored in cryo inventory, verify that proper labeling and tracking processes are in place.

- If the laboratory is not in a hospital setting, the inspector should interview the medical director and practice administrator in lieu of interviewing the hospital administrator and a member of the medical staff.

**Procedures:** The laboratory must have well defined procedures for the processing and testing of specimens, culturing of gametes and embryos, transfer of embryos, and cryopreservation and storage of tissues that include the verification of patient identify and the labeling and tracking of specimens and tissues.

**Quality Management:** The Laboratory General Checklist includes requirements for defining quality indicators for pre-analytic, analytic and post analytic processes. Additional measures of quality are also defined in the Reproductive Laboratory Checklist and include the monitoring of clinical embryology outcomes at least annually, a process to ensure that micromanipulation is performed at an acceptable level, and a program to ensure that cryopreservation is capable of providing viable recovery rates.

**Instrument/Equipment Maintenance:** A variety of equipment is used for the testing, processing, and storage of specimens and tissues. The laboratory must define and document routine maintenance and monitoring of all refrigerators, freezers, incubators, and LN2 storage units to detect and prevent equipment failure. It must have a functional back-up policy in place in case equipment begins to fail, as repair or replacement equipment may not be available within the time frame needed to avoid loss of contents.

**Patient Reports/Records:** The laboratory must name and address of the laboratory, patient identification, patient results with reference ranges, sperm morphology classification system, and interpretive comments when indicated (eg, presence of clumps, collection problems) inpatient reports for semen analysis. The laboratory must maintain embryology records for each patient treatment cycle to include the timing of events, outcome of insemination and culture, identification of the individual performing each step, disposition of each gamete/embryo, and records of critical supplies and equipment use for each tissue. It should maintain cryo inventory records in duplicate, with the second set of records in a separate location. The system must allow for reliable inventory control and easy retrieval of tissues.

**Personnel:** Requirements for personnel performing andrology testing are defined in the Laboratory General Checklist. The Reproductive Laboratory Checklist specifies additional requirements for embryology personnel, which includes minimum educational requirements, specific requirements for training on micromanipulation and other ART related technologies, and requirements for providing sufficient back-up personnel to ensure timely embryology services.

**Forensic Drug Testing Laboratories (FDT)**

*Inspection of an FDT laboratory is not limited to the contents of the FDT Checklist, but includes the All Common Checklist (COM) and all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the COM and GEN Checklists. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to All Laboratory Sections*
**Checklist usage:** The Forensic Drug Testing checklist should be used for laboratories performing non-medical drug testing. The FDT program includes both screening-only laboratories and confirmatory laboratories (must be a CAP FDT-accredited or SAMSHA-certified laboratory). The laboratory must follow chain of custody collection processes. All non-negative screening tests must be followed by confirmatory testing, either by the initial screening laboratory or a reference laboratory.

**Inspector requirements:** Inspectors must be actively involved in a CAP-accredited FDT laboratory and familiar with the FDT checklist requirements. The inspector should have working knowledge of high-performance liquid chromatography (HPLC), gas chromatography-mass spectrometry, tandem mass spectrometry, and automated immunoassay methodologies.

**Specimens:** The FDT checklist addresses drug testing performed on urine, hair, and oral fluid samples. If testing is performed on other matrixes, the laboratory must validate the performance characteristics (accuracy, precision, analytical sensitivity, analytical specificity, linearity and carryover potential) prior to implementing patient testing. Specimens for drug testing must follow a strict chain of custody procedure, including testing for adulteration, to ensure it adheres to valid collection and processing steps from point of collection through final test resulting.

**Quality Control:** The laboratory must test quality control specimens at levels above and below the cutoff value for a particular drug, and it must also include blind samples at various intervals within the testing run. The scientific director or designee must evaluate quality control results weekly or at least monthly, if done by the scientific director.

**Testing Procedures:** The laboratory must validate all analytic methods prior to implementing patient testing. All instrumentation and equipment must be properly operated, maintained, serviced and monitored to provide quality results. The laboratory must use high-quality calibrators, standards, and reagents for accurate drug testing results.

**Personnel:** The scientific director must meet the qualifications listed in the FDT Checklist and possess adequate experience in forensic applications of analytical toxicology procedures.
INSPECTING OTHER TYPES OF LABORATORIES

Special Function Laboratories

- Special function laboratories are administered independently of the main clinical laboratory and have a different CLIA number. They generally employ fewer personnel, and they are dedicated to the performance of a highly select group of clinical procedures. If within 15 miles or 30 minutes driving distance from the main clinical laboratory, special function laboratories are assigned to the same inspection team. Examples of special function laboratories include, but are not limited to, blood gases performed by respiratory therapy, and special hematology analyses in pediatrics or oncology clinics.
- **At least four checklists are required**—the Laboratory General Checklist, the Team Leader Assessment of Director & Quality Checklist, the All Common Checklist and the checklist(s) appropriate to the specific function(s). The inspection is scheduled concurrently with the main laboratory inspection.
- **The Team Leader Checklist will be used 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 special function laboratory and main laboratory accreditation process and decision are made independently.
- The responsible hospital administrator and a representative member of the medical staff will be interviewed for every special function laboratory within a hospital.

Affiliated Laboratories

- Affiliated laboratories are located at physically separate sites but are affiliated by management and/or ownership.
- Each site is considered a separate laboratory and has an individual CLIA number. Each site will receive separate inspection fees, materials, checklists, and a separate certificate of accreditation.
- Examples of affiliated laboratories are: (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.** The inspection team leader needs to take into consideration the location of these laboratories when they are inspected at the same time as a laboratory with which they are associated, in order to allow time for the inspection and arrange for transportation if necessary.

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 CLIA number.
- In most cases, the services that are provided correspond with the Limited Service Laboratory Checklist.
• Separate fees, inspection materials, and checklists are required.
• This 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 take into consideration the location of the satellite laboratories when they are inspected at the same time as a laboratory with which they are associated, in order to allow time for the inspection and arrange for transportation if necessary.

Staff-inspected Laboratories

• This program is in keeping with the College’s philosophy of peer review by using CAP-employed medical technologists to review laboratories that are often performing limited testing. Affiliated and/or satellite laboratories located more than 15 miles or 30 minutes from the main laboratory are typically inspected by CAP-employed medical technologists.
• Hospitals with 100 beds or less that perform basic testing (such as that seen in a core laboratory) may also be inspected by the CAP-employed medical technologists. If there is any on-site anatomic pathology, it must be limited to frozen sections and/or accessioning.

Limited Service Laboratories

• The Limited Service Laboratory Checklist is provided as a convenience when inspecting a laboratory or a laboratory section whose scope of services is confined to a small number of commonly performed tests covering multiple disciplines. It relieves the inspector and the laboratory of the burden of completing multiple checklists during on-site visits to such laboratories.
• If a site qualifies as a limited service laboratory, and it is a free-standing entity with its own director and CLIA number, the Laboratory General, Team Leader Assessment of Director & Quality and All Common Checklists must be used with the Limited Service Laboratory Checklist. In other words, the Limited Service Laboratory Checklist cannot be used alone in that setting.
• 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 federal CLIA number, then one copy of the Laboratory General, Team Leader Assessment of Director & Quality and All Common Checklists should suffice 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 Master Activity Menu is divided into a basic list and an extended list of reportable assays. Limited Service Laboratory Checklist usage is determined by the selection of reportable assays-basic list (only) within a subdiscipline. If assays are selected from the basic list and the extended list of reportable assays, the discipline-specific checklist will most often be used.
• The Limited Service Laboratory Checklist cannot 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.
• LAP staff make the final determination regarding use of this checklist.
**Waived Test Requirements**: Certain checklist requirements are now different for waived tests versus nonwaived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 42).

**System Inspection Option**

The system option for laboratory accreditation provides laboratory directors the choice to have multiple laboratories under the same ownership and administration inspected by one team of inspectors using the same checklist versions within a few days of each other. A system is composed of laboratories with highly integrated services meeting specific eligibility requirements. This provides the opportunity for coordinated laboratory preparation and development of common strategies to comply with the CAP requirements and allows key personnel with responsibilities at multiple sites to participate in the on-site inspections.

**Definition of a System**

A system is defined as two or more full-service laboratories that identify themselves as a system and have common administration and ownership with all laboratories within three hours travel time (ground transportation) of a system-defined central location.

**System Option Eligibility Criteria**

Each individual laboratory within the system must meet the following criteria:

- Use the same administrative policies
- Report directly to a central management team
- Have a common competency policy for common instruments and procedures
- Participate in a system-wide continuous 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

The degree of integration within the system is a major determinant in a system meeting eligibility requirements and thereby remaining in the system option.

**Pre-inspection Activities**

Approximately six to seven months prior to the laboratory’s anniversary date, an LAP inspection specialist will conduct a pre-inspection visit or a conference call to determine the system’s level of integration of services. The LAP inspection specialist will dialogue with members of the system administration and management team to gather information and to better understand the logistical requirements for the upcoming inspection. The information obtained by the inspection specialist will be forwarded to the team leader to assist with inspection planning and the team building process. Examples of the tools that will be used during this visit are available on the CAP website at [cap.org](http://cap.org): Click on Accreditation and Laboratory Improvement, and select
Preparing to Perform a System Inspection

In general, 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. The CAP Travel Desk staff will arrange for direct billing of airfare and lodging and will negotiate the best rates for both.

Upon receipt of the inspector’s packet and the preinspection report, the team leader will determine how many inspectors and how many days will be needed to complete the inspection. The CAP recommends that inspection teams use inspectors who can inspect multiple areas; this will decrease disruption of services at the laboratory and will decrease on-site inspection costs. To assemble your team, please use the information sent to you by the inspection specialist who performed the preinspection visit, and the team building spreadsheet tool that is included in the packet. Share your plans with the inspection specialist and the LAP inspection assignment specialist to determine if there is agreement on team size, composition, time allocation, and the preferred week the inspection will occur in accordance with the inspection specialist’s schedule.

Prepare for the inspection well before the inspection dates. Be clear on 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 appropriate portions of the Anatomic Pathology and/or Cytopathology Checklists. All Deficiency and Recommendations pages are to be addressed during the inspection. If you believe a page is not needed, contact the inspection specialist assigned to your team to explain your rationale and thereby reduce the need to perform reinspection(s).

A coordinated inspection with the AABB inspector 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. If you have any questions either as you prepare for the inspection or at the time of the on-site inspection, call 800-323-4040 ext. 6065 to consult with a technical specialist at the CAP.

Review the remainder of this manual for additional information on preparing for and performing a CAP inspection.

Inspection Tools Specific to Systems

One of the goals of a system inspection is to provide continuity in the inspection process. Therefore, the inspector who inspects a given discipline should be the one inspecting this discipline in all labs. If this is not possible, all inspectors inspecting the same discipline must discuss the findings between laboratories to ensure a consistent approach and interpretation of compliance.
Supplements to the Systems Inspector’s Inspection Packet

1. The Assessment of System Integration form is completed by the system administration and management team before the preinspection visit. The inspection specialist will review the system integration assessment with the system administration and management team and make any necessary revisions. The completed form will be forwarded to the team leader to assist in team building. The criteria can be used during the global summation conference to discuss the degree of system integration.

2. Planning Guide for Inspector Areas of Responsibility is an Excel spreadsheet the team leader uses to build the team and ensure adequate inspectors are used, as well as ensuring any specialty inspector needs are met. A paper copy of this document is also included in your packet. The paper copy is customized for the system you are inspecting.

3. System Integrated Inspector’s Summation Report is an Excel spreadsheet that will summarize deficiencies and recommendations to facilitate the global summation conference. The inspection specialist accompanying the inspection team will maintain this document and provide a completed copy to the team leader prior to the global summation conference.

System Summation Conferences and the Global Summation

A summation conference should take place at each laboratory inspected. Please see the section in this manual titled, “The Summation Conference,” 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. The System Integrated Inspector’s Summation report that is prepared throughout the week by the inspection specialist will aid in recognizing system-wide deficiencies. It is also common for the inspection team to discuss areas of excellence and strengths noted during the system inspection.
THE INSPECTION REPORT

Inspector’s Summation Report (ISR)

**Part A** of the ISR is used to report any fundamental disparities between the intent of the *Standards* and the activities of the laboratory or the role of the director. **This is confidential information that does not go to the laboratory/biorepository**, but is seen only by the technical specialist, the regional commissioner, and the next inspector.

The inspector’s confidential comments, present in Part A, are pivotal in accreditation decisions, particularly those relating to denial of accreditation. Therefore, these comments should be as detailed as advisable, and should support and supplement the deficiencies cited in Part B.

**Part B** of the ISR includes the deficiencies cited and the team’s recommendations. A copy of Part B of the ISR must be left with the laboratory/biorepository director. The inspector must also provide an explanatory comment in the ISR regarding any unexpected testing encountered, as well as if an inappropriate checklist is included in the packet. 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 additional inspectors were required for that checklist, they are to be identified on the reverse side of the form.

The inspector is encouraged to contact CAP staff prior to or during the inspection if questions arise regarding the ISR pages, checklist usage, or unexpected items in the laboratory’s activity menu.

If after the on-site inspection the inspector realizes something was left out of the ISR, a letter must be written to CAP headquarters explaining the addition, and send a copy of it to the laboratory director.
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.

Presumamation Team Meeting

An effective summation conference begins with the presumamation preparation, a 30–60 minute private meeting of the team leader and the inspection team members. The goal of this meeting is to ensure that both the verbal and written inspection reports are complete and consistent. This meeting provides an opportunity for all the team members to share their overall impressions of the laboratory. This will assist the team leader to complete Part A of the ISR and provide a brief review of the cited deficiencies.

- The team leader should remind team members to record the deficiencies in a clear, concise, and straightforward manner, relating each to concrete information gathered during the inspection process.
- The pink pages of Part B of the Inspector’s Summation Report (ISR) are used to list deficiencies. For each page, the inspector should record the individual checklist item number and a brief description of the reason for the deficiency, providing details about the nature of the noncompliance. State the finding, not the checklist requirement. Reference to a specific policy, analyte, or record allows the laboratory to more specifically address the cited deficiency. This is the official record of the inspection and must be both legible and accurate to allow for appropriate follow-up.
- Recommendations should be listed on the appropriate yellow pages of the ISR.
- A blank ISR deficiency page and a blank recommendation page are provided for contingencies (for instance, reporting the inspection of testing that was not indicated by the laboratory in its reapplication).
- All deficiencies should have been discussed with appropriate supervisors. If, following this discussion, appropriate documentation is provided to show the laboratory is actually in compliance, the deficiency should not be cited.
- On the other hand, if the deficiency is corrected on site, the deficiency remains on the ISR with the inspector adding the written notation “corrected on site, substantiated by ____ (includes the detail regarding how the lab corrected the deficiency.); no response required.” The CAP reserves the right to request documentation from the laboratory concerning how the deficiency was corrected on site.
- The team leader should provide help in resolving any remaining questions the inspection team members might have. For assistance, contact a technical specialist at the CAP at 800-323-4040.

Before concluding the pre summation meeting, the team leader should check that:
1. All areas of the laboratory have been inspected.
2. Every inspection team member has completed a deficiency report (pink sheet) that corresponds to the laboratory section(s) for which he/she is responsible.
3. Appropriate checklist items have been cited and the correct deficiency numbers listed on the pink deficiency sheets.
4. The “No Deficiencies” box has been checked when applicable.
5. The inspector’s contact information has been completed on the back of the Deficiency form.
6. No deficiency forms (pink sheets) or recommendations forms (yellow sheets) have been left blank or unsigned. If there are no recommendations for a particular section, place a check mark next to “No recommendations for this section.”

Summation Conference

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 workday.
• Invitations to attend the summation conference should be extended to the laboratory director and laboratory personnel, as well as the administration and the chief of the medical staff, if applicable.
• The team leader should introduce the inspection team members, noting their inspection assignments.
• The team leader should state that the objectives of the CAP’s laboratory accreditation programs are to improve the laboratory for the benefit of the patient through a voluntary, educational peer-review process.
• 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 processes and assessing their compliance with CLIA and CAP checklist requirements. The inspection team will identify areas that require improvement, share information regarding how other laboratories accomplish compliance, and make recommendations for changes to patient care services.

Presentation of Deficiencies

• The laboratory should encounter no surprises when the inspection report is presented. Findings should have been discussed with the supervisors during the inspection.
• Each team member should begin with a brief self-introduction and a word of thanks for the staff that assisted them in the inspection process. Then the team member should briefly present, in a professional manner, the inspection findings, including the deficiencies identified and areas where the laboratory did particularly well. There should be time to answer questions.
• The summation conference is also an appropriate time to discuss recommendations for improvement, as time permits.
• Any unresolved differences concerning interpretation of the Standards or checklist requirements should be addressed at this time. Unresolved differences should be documented by the Team Leader in Part A of the ISR and left for the regional commissioner to review.
• Unresolved differences and challenges to any deficiency should be addressed by the laboratory director in the laboratory’s deficiency response. This should include supporting documentation that will demonstrate that the laboratory was fully compliant prior to inspection. Challenged deficiencies are referred to the regional commissioner for adjudication.
• The differences among the types of deficiencies should be reviewed by the team leader. Phase 0 does not require any formal response: Phase I deficiencies require a written response, while Phase II deficiencies require both a response and a written plan of
corrective action along with supporting documentation that demonstrates implemention. Examples of documentation include: Policies or procedures edited appropriately and signed and dated by the laboratory director or documented designee; QC or maintenance records; log sheets with data; instrument printouts; purchase orders; photographs; memos signed by recipients; meeting minutes with attendance noted; and e-mail memos with distribution list and a list of those who have read.

• A recommendation is a suggestion for improvement; no response or corrective action is required.
• The written Deficiency and Recommendations forms constitute the official report of the inspection, and a copy is left behind by the team. Remind the laboratory that deficiency responses, including documentation of corrective action, and documentation of the director’s approval of the responses, must be submitted to the CAP within 30 calendar days of the inspection date. There will not be a formal list of deficiencies sent from the College to initiate the laboratory’s corrective action and response to the CAP.
• The laboratory should submit their deficiency response to the CAP and retain a copy in the laboratory.
• Give the laboratory the envelope that contains the response forms and instructions. Explain that 75 days after inspection is the timeframe for receiving an accreditation decision.
• Both the laboratory director and the inspection team leader must sign on page 3 of the ISR.
• The team leader should express the team’s gratitude and extend congratulations to the laboratory and its 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.

Concluding the Inspection

The team leader should:
• Give an approximation of the total number of checklist requirements that were used (each checklist consists of 300 requirements or more) to inspect the laboratory so that those in attendance can put the number of identified deficiencies into perspective.
• Thank the director for supporting the CAP accreditation process.
• Photocopy each page of the ISR Part B and leave the copy with the laboratory director.
• Give the envelope containing deficiency response instructions to laboratory personnel.
• Ensure that the team discard at the laboratory/biorepository the checklists and other documents that were used during the inspection; any remaining inspection materials should be discarded confidentially (i.e., shredded).
• Place all deficiency and recommendation pink and yellow ISR pages (including any that might not have been used), along with pages 1–3 of the ISR part A and the ISR Index Page in the prepaid mailing envelope and return to the CAP within 24 hours of the inspection. This mailer can be used in the 48 contiguous states. Materials from inspections outside the 48 states (eg, overseas countries, Alaska, and Hawaii) should be returned to the CAP in the prepaid envelope after returning to the USA.
• The Claim for Inspection Reimbursement form, Team Leader/Member Evaluation form, and signed state-specific forms (if applicable) may be returned to the CAP with the ISR or later.
• Send a postinspection letter thanking the director for the laboratory’s hospitality.
**The College 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, an inquiry is faxed to the laboratory director, requesting that documentation be sent to the CAP within 10 days.
- The completed documentation is then forwarded to the regional commissioner.
- The regional commissioner may request additional information prior to making an accreditation decision. This may include changing a recommendation to a deficiency in cases where the laboratory is clearly noncompliant.
- When all documentation is complete, the regional commissioner makes an accreditation decision recommendation to the Accreditation Committee.

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

1. Certificate of accreditation
2. Letter of accreditation that includes a list of CAP-accredited disciplines/subdisciplines and CMS specialties/subspecialties, and requirements for continuing accreditation
3. Final list of deficiencies
4. Press release
POST-INSPECTION

Expense Reimbursement

Reimbursement expense claims for all team members may be returned to CAP headquarters with the inspection packet or later. **Return of the completed ISR 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. Submit all reimbursement claims 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 all members of the inspection team should complete a Team Member Evaluation questionnaire.

Return of Inspection Packet

To return the inspection report within 24 hours, from anywhere in the US (including Alaska, Hawaii, and Puerto Rico), a FedEx prepaid return label is provided:

- Take the shipment to your institution’s mail center for pick-up by FedEx, or
- Give the shipment to any FedEx driver making a regular pick-up, or
- Take it to any FedEx authorized shipping location. Use either the FedEx website or call 800-GoFedEx (800-463-3339) for the nearest location.
- For a special pick-up, use the website fedex.com or call 800-GoFedEx at the number above.

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.
POST-INSPECTION PHASE

Responding to Deficiencies

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

- Set of instructions for completing responses to any deficiencies cited during the inspection;
- Blank deficiency response sheet;
- Deficiency response signature page to be signed by the laboratory director and returned with the response;
- Laboratory-specific activity menu for the laboratory’s review;
- Checklist Selection Report identifying the checklists that will be used at the on-site inspection;
- Set of customized checklists that reflect the activity menu provided by the laboratory during reapplication. The customized checklists are identical to those that will be used by the inspection team.

Additional copies of the signature page and deficiency response sheets are available on the CAP website. Under the Accreditation and Laboratory Improvement tab, select View in e-LAB Solutions, and choose LAP Resources for Laboratories.

On the day of inspection an envelope containing an additional set of deficiency response instructions and blank forms will be given to laboratory personnel by the inspection team.

A copy of the deficiencies and recommendations is provided to the laboratory at the conclusion of the inspection. **This copy 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 following the routine inspection, or 10 calendar days following a non-routine inspection. Failure to respond may result in denial or revocation of accreditation.**

**Phase II** deficiencies require a written response and supporting documentation demonstrating compliance. The response should explain the purpose of the documentation submitted. The corrective action must meet with the approval of the Accreditation Committee before accreditation is granted.

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

**Phase 0** citations do not require a response to the CAP.

Recommendations are suggestions for improvement, and the laboratory is not obligated to respond to or implement them. A recommendation that should have been cited as a deficiency will be changed to a deficiency by CAP staff or by the regional commissioner, and a deficiency response will be required from the laboratory.
Some examples of supporting documentation include but are not limited to: New or revised policies and procedures with evidence of review and approval; log sheets with evidence of use-blank logs are unacceptable; evidence of staff review or retraining on existing, new or revised procedures; internal memos; photographs, floor plans, and blueprints; purchase orders; and meeting minutes. The response to each deficiency should be on a separate response form page with appropriate documentation of deficiency correction attached to each, label each page of the documentation with the deficiency item number (eg, GEN.10000). Documentation should be submitted in the order the deficiencies were cited in the ISR. It is recommended that updates and changes to existing documents be highlighted.

In accordance with HIPAA, documentation submitted to the CAP must not include any protected health information (PHI), such as patient information. In order to properly de-identify patient information, submitted documentation must not contain any of the following patient identifiers:

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;
Electronic mail 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; and
Any other unique identifying number, characteristic, or code.

**Challenging a Deficiency**

Deficiencies cited by the inspection team may be challenged. Dialogue between the laboratory director and the inspection team leader strengthens the program and can provide insight to both the director and the team leader. Such discourse may lead to changes in checklist requirements or clarification of requirements.

If a decision is made to challenge a deficiency, the intention must be clearly stated on the deficiency response form (ie, I wish to challenge this deficiency), and *attach documentation supporting the claim that the laboratory was in compliance prior to the inspection*. **Challenges must be made at the time initial responses are submitted.** Do not modify current practice 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**

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. Other more extensive deficiencies, such as the lack of a quality management plan, lapses in performance or review of quality control or proficiency testing, or implementation of a new or significantly changed procedure, cannot be corrected on site. When a change to a process, policy, or procedure requires additional training or retraining of personnel, the deficiency cannot be corrected on site. In all cases, the inspector must indicate on the deficiency form how the deficiency was corrected.

**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.

**Deficiency Response Review**

Upon return of the inspection packet from the inspection team leader to CAP headquarters, an audit of the packet and review of the ISR is performed by the laboratory accreditation staff to ensure that the material is complete. All deficiency responses and documentation of corrective action from the laboratory are thoroughly reviewed. Additional responses or documentation may be requested from the laboratory if the original response does not demonstrate compliance with CAP requirement(s).

The inspection report is then forwarded to the regional commissioner. If the responses adequately address the deficiencies, the regional commissioner will notify the laboratory that accreditation is recommended.

**Accreditation**

The decision to accredit a laboratory is made by the Accreditation Committee based on the recommendation of the regional commissioner. This occurs when the laboratory has provided acceptable documented responses to Phase I and Phase II deficiencies and satisfactorily documented correction of all Phase II deficiencies.

Upon recommendation of accreditation:
- The official accreditation letter is sent from the College to the laboratory director, with copies to the administration where applicable.
- The laboratory will receive a press release and a final list of deficiencies.

**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. However, if the**
accreditation decision process goes beyond the accreditation anniversary date, the laboratory’s accreditation is maintained in its current state until that decision is made. During this period, in situations where the laboratory is requested to demonstrate continuing accreditation, a letter may be requested from the CAP that verifies 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 included in the next inspection packet.

Immediate Review Criteria

Immediate review criteria flag a laboratory’s inspection report for expedited processing by CAP staff and the regional commissioner. This occurs when a laboratory is cited for deficiencies on more than 2.5% of the total possible Phase II requirements and/or when a directorship issue is cited by the inspector.

In the past, laboratories with such large numbers of deficiencies have had difficulty correcting them within the allotted time. Following the review of these laboratories, the regional commissioners take such actions as:

- Directly communicate with the director and the state commissioner to determine whether correction is probable
- Recommend to the Accreditation Committee a focused reinspection of the problem areas
- Recommend probation, suspension, or denial of accreditation

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, any agencies accepting CAP accreditation, including but not limited to the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission, are notified.

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

1. Facts surrounding the decision to accredit are unclear.
2. The Accreditation Committee wishes to monitor the progress of the deficiency correction.
3. Laboratory conduct is contrary to the policy of the Joint Commission.
4. 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:

1. Lack of director oversight
2. Patient identification issues
3. Quality control issues that place patients at risk
4. International normalized ratio (INR) issues
**Probation With Suspension** may occur if either of the following conditions is present:

1. The laboratory has deficiencies that may pose a substantial risk of harm to patients or to laboratory personnel, and the Accreditation Committee either:
   a. Needs time to evaluate the situation further, or
   b. Concludes that the deficiencies can be corrected within a specified period.
2. The laboratory has failed to enroll in an accepted approved proficiency testing program or has failed to meet proficiency testing performance criteria.

In general, the suspension aspect is to be resolved within 45 days. The Accreditation Committee will then need to either 1) be confident the laboratory’s suspended section has sufficiently addressed the issues to the degree the suspension decision can be reversed, or 2) revoke the accreditation of the entire laboratory. The laboratory can officially cease all testing in that section.

**Denial or Revocation of Accreditation**

Accreditation is denied or revoked when the laboratory fails to meet any of the standards within the CAP’s laboratory 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 for Laboratory Accreditation*. 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 with numerous deficiencies that cannot be corrected within a reasonable period may be presented to the Accreditation Committee for an accreditation decision.

Laboratories undergoing formal denial or revocation of CAP accreditation will receive notification by Express mail. Any agencies accepting CAP accreditation, including but not limited to the CMS or the Joint Commission, will be notified.

**Appeals**

The laboratory may appeal denial or revocation within 30 days of receiving documented notice of that decision. A request for reconsideration shall not stay the denial of accreditation. Request for information regarding appeal procedures should be directed to the director of accreditation and regulatory affairs at CAP headquarters at 800-323-4040 ext. 7243 or 847-832-7243.

*For additional detailed information concerning Accreditation probation, suspension, denial, revocation, and appeals, see: Appendix L Excerpts of the Commission on Laboratory Accreditation Policy Manual.*

**Post-inspection Critique**

Upon receipt of the Inspector’s Summation Report from the team leader, the College sends the laboratory director a Post-inspection Critique questionnaire. This questionnaire serves as an ongoing quality assurance tool for the inspection process and is used to make continuous improvements at every level. The laboratory director is encouraged to solicit and include
feedback from laboratory personnel who participated in the inspection and return the questionnaire to the CAP within three months of the inspection.
MAINTAINING ACCREDITATION

Administrative Terms of Accreditation

A CAP-accredited laboratory is obligated to:

- Promptly notify the CAP if the laboratory becomes:
  The subject of an investigation by a government entity (including federal, state, local, or foreign entities), OR
  The subject of a validation inspection, OR.
  The subject of adverse media attention (list each government entity, other accreditation organizations, and/or medium responsive to this point, including relevant dates)
- Promptly notify the CAP if the laboratory discovers actions by laboratory personnel that 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. Incorporate corrective or preventive actions into the laboratory Quality Management Plan.
- Provide an inspection team comparable in size and scope to that required for its own inspection if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participate annually in a CAP accepted proficiency testing program, if applicable.
- Promptly notify the CAP in writing of the following changes in: directorship, location, ownership, insolvency or bankruptcy.
- Promptly notify the CAP when there is a change in the laboratory’s test menu prior to beginning that testing.
- Authorize the CAP to release its inspection and proficiency testing data to the appropriate regulatory or oversight agencies such as CMS, Department of Veterans’ Affairs, Department of Defense, Joint Commission, HFAP(AOA), UNOS, or state/provincial agencies.
- Submit a completed Self-Inspection Verification Form in the interim year.
- 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 the CAP web site.
- 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.
- Cooperate in any CAP investigation or inspection.
- 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.**

**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. To assist this effort, a Test Menu Change form is
included in the materials sent to the laboratory at the reapplication and self-inspection periods of the accreditation cycle. The form is also available at the CAP website.

An accredited laboratory must also accept and adhere to the Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design, if the laboratory is using or will use the CAP certification mark of accreditation. The agreement may be downloaded and printed from the CAP website.
Proficiency Testing Participation

The laboratory must participate in a CAP-accepted PT program (see glossary for the definition of CAP-accepted PT program) for all analytes designated by the CAP. (For PT enrollment requirements, refer to the Master Activity Menu with PT Options, available through e-LAB Solutions, or the Analyte/Procedure Index section of the CAP Surveys or EXCEL Catalogs.) The CAP does not accept all CMS-approved PT programs. The CAP accepts PT programs on an analyte by analyte basis, and each PT provider maintains its own list of accepted analytes. Please contact your provider to verify CAP acceptance. The CAP will send a “nonparticipation” proficiency testing compliance notice (PTCN) if there is no PT score for an activity indicated on the laboratory’s menu when participation is required. When the laboratory responds to a compliance notice it must identify the cause of the problem and describe the action it has taken to correct it and to prevent recurrence of the issue. For assistance with troubleshooting nonparticipation issues, please refer to the CAP’s PT Troubleshooting Toolbox available through e-LAB solutions.

Laboratories will not be penalized if they are unable to participate in an oversubscribed program. If unable to participate, however, the laboratory must implement an alternative assessment procedure for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, the CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

If enrollment in a CAP-accepted PT program is not required for a particular test or if PT material is not available for a required event, the inspector must verify that the laboratory performed and documented an alternative method to assess its analytic performance for that test. Alternative assessment may include:

• Participation in a PT product supplied by the CAP or other providers
• Split sample analysis with reference or other laboratories
• Split samples with an established in-house method, assayed material, and regional pools
• Participation in ungraded/educational proficiency testing programs also satisfies this checklist requirement
• Clinical validation by chart review, or other suitable and documented means

Alternative assessment that allows for comparison of results with external laboratories (PT product, split sample with external laboratory, split sample with regional pool) may provide more information than split sample analysis using internal methods. Acceptability criteria for alternative assessment (eg, results within 10% of a reference method) must be defined.

It is the responsibility of the laboratory director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

Alternative assessment must be performed semiannually on tests for which PT is not available.

In some circumstances, certain tests may be performed intermittently, or for a short period of time (for example, tests done in support of research protocols, or tests related to seasonal diseases such as influenza). In such cases, either PT or alternative assessment must be performed within 30 days prior to restarting patient testing; method performance must be
verified, as applicable, within 30 days prior to restarting patient testing; and competency assessment for analysts must be performed within 12 months prior to restarting patient testing.

**Proficiency Testing Performance**

The CAP monitors proficiency testing (PT) scores from all CAP-accepted PT programs (see glossary for the definition of CAP-accepted PT program) for laboratories accredited by the CAP. This monitoring is performed approximately seven to 10 days after the PT program evaluates the results. The CAP compares individual laboratory PT scores to established criteria of acceptability. If the performance of an analyte or subspecialty falls below the acceptable criteria, a proficiency testing compliance notice (PTCN) packet of information is sent to the laboratory. For PTCN’s that do not require a response, which includes first time PT compliance notice for any analyte or subspecialty, the inspector will review the documentation of the investigation and corrective action during the on-site inspection. Refer to the PT Troubleshooting Toolbox on e-LAB Solutions for help with investigating PT failures.

The laboratory should investigate each unacceptable PT result, and document the investigation and the specific corrective action taken to prevent recurrence of the problem, and determine if patient results were affected regardless of whether the documentation is returned to the CAP for review. For those results that were not graded (identified by a nongraded reason code), please refer to Appendix I for appropriate action.

CAP technical staff will review the laboratory’s PTCN response and will request additional documentation if the response is incomplete. This request for additional documentation includes a response due date and requires a written response. CAP staff may also provide informational letters with recommendations to assist the laboratory with improving their current testing processes for the analyte or subspecialty in question. A participant response is not required for these informational letters.

The CAP not only tracks unacceptable performance of an analyte or subspecialty for the current testing event, it also tracks trends of unacceptable performance of PT scores from previous testing events. When PT performance is unacceptable for multiple testing events, the laboratory should provide documentation encompassing all of the unacceptable testing events and make note of the presence or absence of trends. Recurrent PT failures (three of four of the last testing events) are especially critical. The laboratory’s responses and corrective actions to recurring failures (repeat unsuccessful) are thoroughly examined. Reinspection and/or sanctions to the laboratory’s accreditation may result including a mandate to cease patient testing until requirements are met.

To assist its on-site inspectors, the CAP includes a report and a synopsis of PT performance variances in the Inspector’s Inspection Packet. The report flags every occurrence of an unacceptable result since the last inspection and the synopsis report flags repeated unsuccessful PT performance. The inspector will review records of calibration frequency, quality control results, validation of the analytical measurement range, and troubleshooting logs from the time periods for PT variances.
Avoiding a Proficiency Testing Referral Citation

Among the items cited in the Clinical Laboratory Improvement Amendments (CLIA) law and regulations (section 493.801) are the requirement that all laboratories must enroll in approved proficiency testing programs and that the laboratory must test samples in the same manner as the laboratory tests patient specimens. This means PT samples should be tested along with the laboratory’s regular workload by personnel who routinely perform the testing. Therefore, if a laboratory runs a patient specimen only once, PT specimens must also be run only one time. It also means that PT samples should be rotated among all staff members and all shifts that routinely perform the patient testing.

The CLIA regulation specifies that a laboratory cannot refer any PT material for testing to another laboratory. Therefore, if a laboratory typically performs patient sample testing to a certain point and then sends out some of the sample for additional testing, it must not do so with the PT samples. The lab must only report the testing completed in its own laboratory. The sole exemption is for laboratories that refer processing of HER2 slides by immunohistochemistry (IHC) to another laboratory, but perform the interpretation in-house. In that case, the processing (and only the processing) of the PT slides may be referred to the usual outside laboratory.

If you have additional questions on PT requirements for breast predictive marker testing (HER2/ERPgR) refer to the frequently asked questions on cap.org (PT toolkit).

The penalty for violating this regulation, according to the Centers for Medicare & Medicaid Services (CMS), may be “revocation of the laboratory’s certification for at least one year” and the potential prohibition of the owner or medical director to own or direct a lab for two years.

**e-LAB Solutions:** Laboratories using CAP Surveys can submit PT results online and view their scores online using e-LAB Solutions. Accredited laboratories may view a report that lists analytes with PT scores of less than 100% (PT exceptions that require follow-up). With this report, a laboratory can easily track its PT exceptions directly online. If a response to the CAP is required, the laboratory can download a prepopulated response form, complete its performance investigation on a real-time basis, and fax documented corrective action to the CAP for efficient resolution of any PT issues.

**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. (It is likely that the checklist version sent for use in the self-inspection will be different from the version used for the previous or next on-site inspections.) The laboratory must perform the self-inspection and return the self-inspection verification form signed by the director within 60 calendar days after receiving the self-inspection materials. The verification form states that the laboratory will correct all deficiencies cited, and that documentation of corrective action will be kept on file for review by the next CAP inspection team, which will observe to see if all deficiencies noted on the self-inspection, have been corrected. Deficiencies should be corrected within 30 days of the self-inspection similar to deficiencies cited by an on-site inspection team. The laboratory should keep the self-inspection checklists 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 laboratory 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 accreditation anniversary date.**

Implications of Accreditation/Recognition by Accrediting Organizations and Other Government Agencies

Certain regulatory agencies and other accrediting programs officially recognize the value of the CAP’s laboratory accreditation programs. Upon request, those regulatory agencies that have a relationship with the CAP program and the accredited laboratory will be sent necessary data. The regulatory and accrediting agencies that may receive copies of the inspection report are listed in the following section.

**The Joint Commission**

Hospitals seeking Joint Commission accreditation may choose to accredit the hospital laboratory through the CAP program. The Joint Commission accepts CAP accreditation of hospital laboratories. Generally, a Joint Commission laboratory surveyor will not survey CAP-accredited laboratories in Joint Commission-accredited hospitals. During the hospital's survey, however, an administrative surveyor will 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 will occasionally validate the CAP inspection process by sending an observer along with a CAP inspection team.

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

The LAP 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 significant obligations upon the LAP. The fixed accreditation cycle must be honored by ensuring that laboratories are inspected every two years. In addition, CLIA requirements have been incorporated into the inspection checklists. Within each facility, CLIA certificates and CAP accreditation data must be concordant, (e.g., one CLIA number corresponds to one CAP number). CMS validates the CAP inspection process by sending surveyors to a representative sample 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 extent to which the CAP accreditation program is recognized by state governments varies. The College will make the results of the accreditation decision available to a state agency upon request from the state agency.

The inspector can determine the accreditation implications of the current inspection by reviewing the "Release of Data" form in the reapplication material. The director's signature on the form indicates acknowledgement that the CAP may provide accreditation information to related agencies.
NON-ROUTINE INSPECTIONS

The regional commissioner may request an on-site inspection outside of the routine accreditation cycle. The inspection may be announced or unannounced. For announced nonroutine inspections, a letter explaining the process and a request for the inspection fee will be sent to the laboratory director. The laboratory and the individual performing the nonroutine inspection will receive checklists for the laboratory section(s) being inspected. The Inspector’s Summation Report (ISR) will indicate the time allowed the laboratory to respond to any deficiencies found during this out-of-cycle inspection. The technical specialist and the regional commissioner will review the deficiency responses in the usual manner.

Nonroutine inspections may occur under a variety of circumstances (see below); a fee is assessed for this type of inspection. On the day of inspection, the inspector(s) will present a letter explaining the process, and proceed with the inspection in the usual manner. A Summation Conference will be held at the end of the inspection. The laboratory is generally given 10 days to return to CAP documentation of correction of any deficiencies identified.

Change in Location, Director, or Ownership

Accreditation by the CAP does not automatically continue after there is a change in location, director, or ownership. Notification of such changes must occur no later than 30 days prior to the change(s); or, in the case of unexpected changes, no later than two working days afterwards, in order to satisfy CLIA requirements. Additional information may be requested from the laboratory.

Note: A change in location is defined as an actual physical change of premises of operation, whether or not there has been a change in address.

If after reviewing the laboratory’s initial documentation, the regional commissioner finds that no substantive changes in the operation of the laboratory have been made and that all the requirements of the Standards for Laboratory Accreditation are met, the commissioner may waive reinspection and shall notify the College in writing of his or her recommendation. The laboratory will retain its accreditation until the next regularly scheduled inspection.

Added Discipline

An on-site inspection is used routinely for labs that add anatomic pathology, cytology and/or hitocompatibility testing.

If the laboratory adds a clinical pathology discipline (eg, flow cytometry, cytogenetics), the laboratory will be required to perform a self-inspection using customized checklists provided by CAP. The self-inspection verification form must be signed by the medical director and returned to CAP within 30 calendar days of receiving self-inspection materials. If, after reviewing these materials, the regional commissioner determines this added discipline requires an inspection before the laboratory’s next scheduled on-site inspection, assessed non-routine inspection will be performed. If a non-routine inspection is not requested by the regional commissioner, a revised accreditation letter extending accreditation for the added discipline will be sent to the laboratory.
Secondary On-site Inspection

This inspection occurs within the regular inspection cycle and is conducted after an on-site inspection. The regional commissioner requests a second visit by a specialized team of inspectors to document correction of selected deficiencies in one or more specific disciplines. This may occur if the laboratory failed to report all testing activities and therefore not all testing was inspected. A secondary inspection may also take place when the deficiencies cited are so profound that the regional commissioner judges paper documentation of deficiency correction inadequate. A fee is assessed unless the reason for the inspection is due to an error on the part of the CAP (e.g., inspector missed the section, or the appropriate checklist was not supplied to the inspector).

Proficiency Testing Compliance Notice (PTCN), Nonroutine Inspection

This inspection usually follows the same process as a secondary on-site inspection, and can take place at any time during the accreditation cycle. The Continuous Compliance Committee (CCC) of the Commission on Laboratory Accreditation will request this inspection when there is evidence of repeated non-compliance with proficiency testing performance standards. LAP staff and the CCC will review the response. A fee is assessed for this inspection.

Complaints

A complaint is the formal notification to the College or the discovery by the College 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.

The Complaint Process

As soon as the College receives a complaint, the complaint investigation process is initiated. Depending upon the nature of the complaint, the investigation can include a request for information from the lab, a search of past inspection and proficiency testing results, or even an unannounced on-site inspection.

This inspection usually follows the same process as a secondary on-site inspection and can take place at any time during the accreditation cycle. The Complaints and Investigations Committee will request this inspection when there is a concern for noncompliance with the Standards for CAP Accreditation in a currently accredited laboratory. CAP staff, the regional commissioner, and the complaints commissioner will review the response. Fee assessment is determined on a case-by-case basis. Alternatively, complaint investigations may be conducted as part of a routine on-site inspection if the timing is appropriate.

Based on the findings of the investigation, the CAP Accreditation Programs Complaints and Investigations Committee will review the findings of the investigation and determine whether the complaint is substantiated as well as the appropriate course of any further action, if any. The CAP recognizes that no two laboratories are exactly alike. Therefore, the course of action decided upon by the committee is tailored specifically to address any problems discovered during the investigation. Any accreditation decision is made by the CAP Accreditation Committee on a case-by-case basis. In addition, all substantiated complaints and/or changes in accreditation status will be shared with state and federal accreditation agencies.
Appendix A:
CAP Checklist Usage

This appendix does NOT include all possible uses for a particular checklist. To verify checklist usage, contact the CAP at 800-323-4040 ext. 6065.

Laboratory General — Used to inspect all areas of the laboratory for quality management, specimen collection, results reporting, computer services, personnel, space, and safety.

All Common — Used to inspect all areas of the laboratory for proficiency testing, procedure manuals, critical results, and method performance specifications.

Anatomic Pathology — Used for all surgical pathology, including frozen sections, histology/histopathology, immunohistochemistry, autopsies, and electron microscopy. The Anatomic Pathology Checklist can also be used to inspect laboratories performing FISH (eg, HER2) and ISH (eg, HPV) techniques in histologic sections and fine-needle aspiration specimens (FNA) in surgical pathology. The Cytopathology Checklist must be used if FNAs are screened by a cytotechnologist. Laboratories that only accession tissue specimens should not use the Anatomic Pathology Checklist.

Chemistry and Toxicology — The Chemistry and Toxicology Checklist is used for:
• Common chemistry tests typically performed on automated and semiautomated instruments;
• Toxicology testing, including all screening and/or confirmatory testing for drugs of abuse, legal alcohol analysis, and other toxicology tests, regardless of methodology;
• Blood gas analysis and oximetry;
• Assays performed by flame photometers, atomic absorption, spectrophotometers, immunoassays, including enzyme immunoassays (EIA) and radioimmunoassays (RIA), GC/MS, TLC, HPLC, and electrophoresis;
• Therapeutic drug monitoring (TDM), prenatal screening for fetal anomalies, abnormal hemoglobin detection, and cystic fibrosis screening.

Clinical Biochemical Genetics — Used to inspect sections performing biochemical techniques for metabolic disorders.

Cytogenetics — Used for amniotic fluid cell analyses, bone marrow cultures, chorionic villus studies, Fragile X studies, blood lymphocyte analyses, solid tumors, and nonneoplastic tissue cultures. Biochemical genetics testing (eg, amino acids analysis) is inspected with the Clinical Biochemical Genetics Checklist.

Cytopathology — Used for all gynecologic and nongynecologic cytopathology, including processing, screening, pathologist evaluation, liquid-based methods, and automated screening instruments. Laboratories that only accession cytology specimens should not use this checklist.

Immunology — Used for syphilis testing by fluorescent and/or serologic methods, and for nonsyphilis serology testing such as hemagglutination, immunoassay, immunofluorescence, and direct antigen detection.
**Flow Cytometry** — Used to evaluate flow cytometry assays, including DNA analysis, lymphocyte phenotyping, leukemia/lymphoma immunophenotyping, and CD34 stem cell enumeration.

**Forensic Drug Testing** – Used for laboratories performing drug testing for non-medical purposes (i.e., workplace drug testing). This checklist is to be used only by laboratories enrolled in the Forensic Drug Testing Program.

**Hematology and Coagulation** — Used for blood cell counts and differentials, coagulation testing, bone marrow analysis, body fluid analysis, examination of blood films for malaria and other parasites, and abnormal hemoglobin detection.

**Histocompatibility** — Used for all transplant tissue compatibility studies, including HLA typing, crossmatching, HLA antibody screening and identification, and mixed lymphocyte culture testing. The Histocompatibility Checklist is used to inspect HLA testing performed by serological, immunoassay, flow cytometry, and molecular methodologies.

**Limited Service Laboratory** — Used for freestanding laboratories or a section of a laboratory doing a limited number of basic tests in multiple disciplines (e.g., outpatient or “STAT” labs). This checklist is not appropriate for single-discipline or specialized laboratories; these laboratories must use the appropriate 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 for medical purposes and serum or whole blood medical 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 and virology, and molecular microbiology, including DNA testing using amplified and nonamplified methods. Limited Service may be used for direct antigen testing for all microbiology subdisciplines.
- **Transfusion medicine** — any testing other than ABO/Rh and antibody screening (nontransfusion), 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** — Used for bacteriology, mycobacteriology, mycology, parasitology, virology, and molecular microbiology. Microbiology laboratories performing FDA cleared/approved nonamplification methods, FDA cleared/approved target and signal amplification methods and sequencing, or laboratory developed or modified FDA cleared/approved tests may use the Microbiology Checklist.

**Molecular Pathology** — Used for molecular techniques for oncology, genetics, parentage, forensic identity, and *in situ* testing.
**Point-of-Care-Testing** — Used for point-of-care-testing (POCT) performed in nondedicated space (e.g., with portable instrumentation). A discipline-specific checklist(s) may be required in addition to the Point-of-Care-Testing Checklist if certain analytes performed in nondedicated space warrant its use. Dedicated laboratories 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. The Point-of-Care Testing Checklist is used to inspect provider-performed testing that is under the responsibility of the laboratory director.

**Reproductive Laboratory** — Used for laboratories performing andrology testing and procedures (e.g., semen analysis and preparation for therapeutic insemination), embryology procedures, and cryopreservation of gametes and embryos. This checklist is to be used only by laboratories enrolled in the Reproductive Laboratory Accreditation Program.

**Team Leader Assessment of Director & Quality** — Used by the inspection team leader to evaluate the laboratory director and provide an overall evaluation of the quality management program of the laboratory.

**Transfusion Medicine** — Used for blood, blood component, tissue storage, compatibility testing, transfusion services, donor collection, component preparation, bone marrow and/or progenitor cell services, and blood group parentage testing. Laboratories with immunohematology testing limited to ABO, Rh, antibody screens (nontransfusion), and direct antiglobulin testing may be inspected with the Immunology Checklist.

**Urinalysis** — Used for automated and semiautomated urinalysis, dipsticks and dipstick readers, morphology systems, and microscopic urinalysis.
Appendix B: Guidelines for Determining Test Volume

Test volumes are requested for each laboratory section and are separated into the following categories:

**CMS-reported** — Includes test volumes for all high and moderate complexity testing performed in each section. This information is reported to the CMS annually. Do not include calculations (e.g., A/G ratio, MCH, base excess, anion gap, iron saturation, INR), quality control, quality assurance, or proficiency testing assays.

**CMS-nonreported** — Includes test volumes for waived testing and other tests or procedures to be inspected that are not classified by the CMS (e.g., autopsy and employee drug testing) for each section. These totals are used for on-site inspection planning only.

*Note: International laboratories that do not have a CLIA license should report all of their test volume in the CMS non-reported category.*

**Specialty information:**

**Chemistry:** For profiles, each individual analyte is counted separately.

**Cytogenetics:** The number of tests is determined by the number of specimen types processed on each patient (e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests).

**Cytology:** For CMS statistics, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.

**Hematology:** For complete blood counts (CBCs), each measured individual analyte ordered and reported is counted separately. The white blood cell (WBC) differential counts as one test.

**Histocompatibility:** Each HLA typing (including disease-associated antigens), HLA antibody screen, and HLA crossmatch is counted as one test.

**Histopathology:** For CMS statistics, each block (not slide) is counted as one test. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.

**Immunohematology:** Each ABO, Rh, antibody screen, crossmatch, or antibody identification is counted as one test.

**Immunology:** Testing for allergens should be counted as one test per individual allergen.

**Microbiology:** Susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification.

**Urinalysis:** A microscopic examination is counted as one test. A macroscopic (dipstick) examination is counted as one test, regardless of the number of reagent pads on the strip.
Appendix C:
Unannounced Inspection: Tips for Laboratories and Inspectors

Tips for Laboratories

Prior to the Inspection

1. Remind relevant hospital medical and administrative personnel of the unannounced inspections (a template letter is available at cap.org; Laboratory Accreditation; Resources for Labs). Ask for their support, as well as for contact information for primary and backup individuals and, for who would be available for interviews by the inspection team on the day of inspection.

2. For each area of the laboratory, identify primary and back-up staff who will have knowledge of procedures, policies, and the location of key documents (eg, QC, PT, QM, training and competency, instrument validation, AMR records).

3. Identify inspection day tasks and assign primary and backup staff for each task (see sample task list).

4. Develop a phone list of primary and backup staff who will be contacted upon arrival of the inspection team. List should include chief executive officer (CEO), medical chief-of-staff, medical director, laboratory director, laboratory manager, and section supervisors. If the lab needs additional full-time employees (FTEs) on the day of the inspection, a list of employees who have previously indicated the ability to work on short notice should also be available.

5. For each checklist requirement, note the location of documents or records that demonstrate compliance. This may be a good opportunity to have department staff review the requirements and attach samples of records or forms as appropriate.

6. 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 know how to locate or retrieve the documents and records.

7. Identify options for workspace that can be used by the team. Space can either be in the laboratory, in an area designated for clerical/administrative services, or elsewhere in the institution, but it must be convenient to the lab.

8. If the inspection team has to travel from site to site, develop maps and identify possible modes of transportation in case the team has not previously made travel arrangements.

9. Train all staff so that they are familiar with the checklists and the inspection process. Unannounced inspections could be an ongoing agenda item at lab meetings that serves to increase communication and provide preparedness updates.
10. Identify and report to the CAP a phone that is attended at all operating hours for the laboratory (e.g., 24/7 for hospital labs, etc). This is the phone number that the inspector will call to provide allowable advance notice of the arrival of the inspection team.

**Inspection Day**

1. Activate the inspection day task list and refer to it as necessary during the day.

**Post-Inspection**

1. Identify successes and develop an action plan for what you might do differently for your next inspection.

2. Make appropriate changes as soon as feasible.

3. Use the self-inspection period to refine your inspection day processes. Have a group of staff (preferably your designated inspection back-up staff) conduct an unannounced inspection of the lab or a section of the lab. This will help you spot areas that you may have overlooked or that need better clarification, and will give your back-up staff the experience of having primary staff explain how the laboratory is in compliance.

4. Continue to communicate with staff, conduct drills, and evaluate the process throughout the two years.

**Sample Inspection Day Tasks**

<table>
<thead>
<tr>
<th>Task/Role</th>
<th>Primary Staff/ Extension #</th>
<th>Backup Staff/ Extension #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated central contact for the inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Secure workspace for the inspection team</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Greet the inspection team at the reception desk and lead them into the lab or to the workspace</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Assess workflow/FTE situation; make appropriate modifications as necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Make appropriate phone calls to notify that inspection team has arrived</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Schedule interviews with CEO and chief-of-staff</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6. Arrange for food and beverages (coffee/water/drinks and lunch)

7. Arrange for off-site records to be delivered

Additional Information

- Please note that the checklist edition sent upon completion of your reapplication will be the edition used for your inspection. The checklists will be customized. For answers to other Frequently Asked Questions, visit the CAP website.
- Taped audioconferences provide more information about unannounced inspections and are available on the CAP website at cap.org.

Tips for Inspection Team Leaders

Prior to the Inspection

1. Communicate with CAP staff to coordinate the inspection. Staff can help clarify any questions that you may have about the inspection and can also help identify additional team members if needed, particularly if a specialty inspector is required for the inspection. It is also permissible to contact the laboratory directly in order to clarify any questions you may have. You may identify yourself and the inspection team’s institution, but you may NOT disclose the date of the inspection.

2. Review the Inspector’s Inspection Packet and plan the inspection. In particular, allow sufficient time for the inspection, especially in light of the unannounced inspection process. Remember to notify the laboratory of your intention to inspect one hour prior to your team’s arrival.

3. When scheduling the inspection day, consider the laboratory’s operating hours and any other applicable holidays (like federal or Canadian). Choose a day when the lab is operating at its fullest capacity (typically a weekday). By doing so, you will be able to assess most, if not all, aspects of lab operations and will likely encounter the appropriate staff that you will need to interview and observe. Be sure to schedule around the laboratory’s indicated blackout dates and any federal or national holidays.

4. If the laboratory that you are inspecting requires security clearance, allow for an extra half hour in the morning for any clearance details to be worked out on site.

5. Things to do when you meet with your team:
   - Distribute appropriate lab information to each inspector on the team.
   - Inform team members to bring identification.
   - Remind team members to be flexible and to keep the inspection moving; if a document is not readily available, an inspector should move to another part of the checklist until the lab has located the appropriate documentation.
• Remind team members to interview lab staff and observe testing to make sure written policies and procedures match actual practice, utilizing the “ROAD” inspection techniques.

6. Ensure that your team members are trained; Web-based sessions are available at cap.org under the Education tab.

**Inspection Day**

1. Call and notify the laboratory of your intent to inspect one hour prior to your arrival.
2. Meet team members at a central location away from the laboratory. Arrive at the laboratory as a group.
3. Assume that breakfast will not be provided by the lab because they are not expecting you. Make your own plans for this meal and arrive at the lab ready to inspect.
4. Present the letter that identifies your team as a group representing the CAP to the lab; wait until the lab verifies the information. Ensure that all team members can provide personal identification, if asked, and have them wear their inspector name badges.
5. Be courteous and patient as the lab organizes its day—it may take them a while to institute their action plan.
6. Meet with your team members throughout the day; keep lines of communication open to ensure that the inspection is proceeding according to plan. Ensure that any deficiencies are discussed with the laboratory as they are identified throughout the day.

**Post-Inspection**

1. Identify successes and develop an action plan for what you might do differently for the next inspection.

Make appropriate changes and evaluate the process with your team members.
Appendix D: Sample of Inspection Confirmation Letter to Laboratory Director

Use this letter for announced inspections only. The team leader should customize and send the template letter to the director of each laboratory to be inspected, including separately accredited blood gas or special function laboratories. The team leader should also place a copy of the customized letter in the inspection packet.

Dear Dr. (...):

This letter confirms our telephone conversation in which we arranged the CAP inspection of your laboratory. We plan to arrive at your laboratory on (...) at about (...) and anticipate that the inspection will last approximately (...).

Assisting me in this inspection will be the following individuals and the areas they will inspect:
(Insert as applicable eg, Laboratory General: (name of inspector)
   All Common: (name of inspector)
   Hematology: (name of inspector)
   Chemistry: (Name of inspector)

We would like to meet with you and your staff briefly at the beginning of the visit to review the day’s schedule and to take a brief walking tour of the laboratory. Team members will then go with the respective supervisors to inspect the departments. If possible, please provide a workspace in an office or conference room that is convenient to the laboratory.

(Insert the paragraph below for hospital laboratories)
Please arrange for brief appointments of 15 minutes each with the hospital administrator and a representative of the medical staff. These meetings help determine whether the laboratory has established an effective working relationship with the administration and staff. Ideally, these meetings should take place about halfway through the inspection.

The inspection will proceed more efficiently if the laboratory has these items of special interest (listed below) readily available. As we go through the checklists, we will review the following:

1. Laboratory General
   a. Personnel policies and complete personnel records (gathered and organized at one site that is convenient to the laboratory)
   b. Quality management plan and records of meetings, studies, etc
   c. Continuing education records
   d. Self-inspection records from last year
   e. A copy of those portions of the hospital nursing manual or doctor office directions that relate to specimen collection and to transfusion of blood
   f. Professional qualifications of all section (general) supervisors; readily available in one location for the inspector
   g. Chemical hygiene plan and annual evaluation of plan
   h. List of all laboratories to which you refer specimens, along with their CLIA numbers
i. Validation records (method performance specifications) for all analytes currently being tested

2. All Common

3. Each department
   a. Procedure manuals
   b. Instrument maintenance records
   c. Quality control and proficiency testing records
   d. Safety manual
   e. Examples of report forms

4. Hematology
   Example slides of Romanowsky and reticulocyte stains

5. Microbiology
   Example slides of Gram stain and other stains

6. Chemistry
   Reference thermometers, reference weight standards, and volumetric glassware

7. Anatomic Pathology
   Reports and slides for at least 10 surgical pathology cases, preferably of various complexities and types, five autopsies, and example slides of all routine and special stains offered

8. Cytopathology
   Final reports and slides from approximately 15 cases (both gynecological and nongynecological cases, positives and negatives, as applicable), as well as qualifications of all personnel, workload records, rescreening documentation, yearly statistics, and other quality management records

9. Cytogenetics
   Examples of normal and abnormal cases for every test method

10. Molecular Pathology
    A sampling of completed case records (five recently completed cases for each of the main types of analyses offered, both normal and abnormal if possible)

We expect to complete the inspection by (x:xx PM) at which time we would like to meet with you and your staff again for the summation conference to discuss the inspection findings. Please invite as many personnel from the laboratory to this meeting as you deem appropriate. We plan to adjourn by (x:xx PM).

(Include this sentence as appropriate)
If you have any suggestions for luncheon arrangements, lodging, or travel directions, please let me know.

We look forward to meeting you and your staff on (. . .).

Sincerely,

__________________________________
Team Leader’s Name
### Appendix E:
Laboratory General Activity Menu Reference Guide

<table>
<thead>
<tr>
<th>Activity Code</th>
<th>Activity Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4469</td>
<td>CLIA certificate of accreditation</td>
<td>CMS-issued certificate for a laboratory performing moderate and/or high complexity testing. The certificate is issued to laboratories who are accredited by accrediting organizations that have deeming authority under CLIA, such as CAP, The Joint Commission, COLA, etc.</td>
</tr>
<tr>
<td>4455</td>
<td>CLIA certificate of compliance</td>
<td>CMS-issued certificate for a laboratory performing moderate and/or high complexity testing. The certificate is issued to laboratories who are currently accredited by the CMS.</td>
</tr>
<tr>
<td>4456</td>
<td>CLIA certificate of registration</td>
<td>CMS-issued certificate for a laboratory performing moderate and/or high complexity testing. The certificate is issued to laboratories as a temporary certificate that allows the laboratory to operate while applying for accreditation.</td>
</tr>
<tr>
<td>4470</td>
<td>CLIA certificate of PPM</td>
<td>CMS-issued certificate for a laboratory in which a physician, midlevel practitioner, or dentist personally performs testing during a patient’s visit, limited to provider performed microscopy (PPM) procedures (defined in CLIA regulations) and waived testing.</td>
</tr>
<tr>
<td>4457</td>
<td>CLIA certificate of waiver</td>
<td>CMS-issued certificate for a laboratory performing testing that is not required to be regulated or accredited.</td>
</tr>
<tr>
<td>4471</td>
<td>CLIA certificate not applicable</td>
<td>The laboratory is not required by law to obtain a CLIA certificate.</td>
</tr>
<tr>
<td>4458</td>
<td>QMS integrated with primary laboratory (primary lab)</td>
<td>The quality management system and documents are substantially integrated across multiple affiliated laboratories. This laboratory is the primary laboratory within the group.</td>
</tr>
<tr>
<td>4459</td>
<td>QMS integrated with primary laboratory (affiliated lab)</td>
<td>The quality management system and documents are substantially integrated across multiple affiliated laboratories. This laboratory is an affiliated lab within the group.</td>
</tr>
<tr>
<td>4460</td>
<td>QMS not integrated with other lab</td>
<td>The quality management system is independent of other laboratories.</td>
</tr>
<tr>
<td>4461</td>
<td>Specimen referral to reference laboratory</td>
<td>The laboratory transports specimens to other testing facilities for analysis.</td>
</tr>
<tr>
<td>4462</td>
<td>Laboratory phlebotomy services</td>
<td>Phlebotomy services are provided by personnel under the control of the laboratory director.</td>
</tr>
<tr>
<td>4463</td>
<td>Specimen collection for compatibility testing</td>
<td>Collection of pretransfusion testing specimens by laboratory employees.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Details</td>
</tr>
<tr>
<td>-------</td>
<td>--------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>4464</td>
<td>Specimen collection for paternity/forensic testing</td>
<td>Collection of paternity or forensic testing specimens by laboratory employees.</td>
</tr>
<tr>
<td>4465</td>
<td>Specimen transport to/from other laboratory</td>
<td>Patient samples are received from remote locations outside of the facility or are sent by the laboratory to other locations.</td>
</tr>
<tr>
<td>4466</td>
<td>Central processing area</td>
<td>Centralized laboratory location where specimens are processed prior to analysis. Processing may include steps such as accessioning, centrifuging or aliquoting.</td>
</tr>
<tr>
<td>323</td>
<td>Laboratory information system – local host</td>
<td>The LIS host (computer facility, equipment, hardware, and software) is physically on the same campus as the laboratory</td>
</tr>
<tr>
<td>324</td>
<td>Laboratory information system – off-site host</td>
<td>The LIS host (computer facility, equipment, hardware, and software) is physically remote from the laboratory</td>
</tr>
<tr>
<td>325</td>
<td>Information system interface(s)</td>
<td>Results are transmitted from instruments to a laboratory or hospital information system.</td>
</tr>
<tr>
<td>4467</td>
<td>Auto-verification</td>
<td>The process by which patient results generated from interfaced instruments and sent to the LIS are compared against laboratory-defined acceptance parameters. Results within the parameters are automatically released without laboratory staff intervention.</td>
</tr>
<tr>
<td>3551</td>
<td>Direct-to-consumer (DTC) testing</td>
<td>Direct-to-consumer tests are defined as tests that are requested or ordered by the consumer.</td>
</tr>
<tr>
<td>4468</td>
<td>Telepathology</td>
<td>The practice of pathology in which the pathologist views digitized or analog video or still image(s) and renders an interpretation that is included in a formal diagnostic report or documented in the patient record.</td>
</tr>
</tbody>
</table>
Appendix F:
Site Coordinator Guidelines

COLLEGE OF AMERICAN PATHOLOGISTS
LABORATORY ACCREDITATION PROGRAM
SITE COORDINATOR GUIDELINES

What Is a Site Coordinator (SCO)?

The site coordinator is the laboratory individual who the medical director has appointed to work directly with the inspection team. There is no requirement to have a SCO, but if the decision is made to do so, the medical director should appoint the SCO as soon as possible so that individual can begin the planning process. The CAP recommends that a SCO be identified for all CAP system inspections and whenever multiple laboratories are being inspected together as a group.

Role of Site Coordinator:

1. Appointed by medical director to facilitate inspection process
2. Responsible for application/reapplication following current requirements of the Laboratory Accreditation Program process
3. Establishes black-out dates for all laboratories being inspected under the Inspection Instance
4. Develops an inspection plan which is initiated either by pre-arrangement for an announced inspection or receipt of one-hour security notice telephone call
5. Facilitates list of key individuals the inspection team will work with
6. Arranges conference rooms
7. Provides refreshments and lunch, if necessary
8. Develops schedule for CMO, CEO interviews
9. Determines mechanism to provide needed documentation for inspection team review
10. Assists with transportation between laboratories, hotels and airports, if required
11. Determines location of summation conference
12. Facilitates photocopying of ISRs
13. Coordinates the deficiency response process
SITE COORDINATOR’S CHECK-OFF LIST
ANNOUNCED INSPECTIONS

Preliminary Tasks

☐ Determine which functions the laboratory director has designated to the site coordinator.

☐ Make sure documentation of correction of deficiencies is complete:
  - From the last on-site inspection
  - From the self-evaluation

☐ Draft an inspection plan, considering all sites included in the inspection.

☐ Make a preliminary list of recommended dates for the inspection.

Telephone Call to Inspector

☐ Determine who will coordinate the schedule and logistics for the inspection team. (Will the inspector team leader appoint a team coordinator?)

☐ Exchange contact numbers, email addresses, etc.

☐ Discuss transportation, start time, start location, hotel suggestions, special needs for team members, etc.

To Be Accomplished Six Weeks Before the Inspection

☐ Request a list of team members, their credentials, assignments, and special needs from the team leader if not already provided.

☐ Ensure that the team has appropriate transportation to and from its hotel.

☐ In concert with the team coordinator, schedule interviews with the:
  - Hospital administrator/chief executive officer
  - Chief of staff/chief medical officer

☐ Prepare the list of laboratory employees who will be working directly with the inspection team, and include their phone numbers and/or pager numbers.

☐ Reserve the meeting rooms:
  - “Home base” or staging area for the team (all day)
  - Introductory meeting (morning)
  - Summation conference (afternoon)
Discuss personal protective equipment (PPE) needs with team leader or coordinator.

Provide the team with a list of recommended local restaurants.

To Have Ready for the Inspection

Establish a mechanism to escort the team members to the individual laboratories:
• For special function labs, determine how inspector will get to the laboratory and back
• For satellite labs, provide for ground transportation

Provide a quiet room convenient to the laboratory where centralized records will be available throughout the course of the inspection.

Have PPE available as needed.

Provide food and drink:
• Arrange for box lunches or simple buffet for a working lunch
• Have cold drinks or coffee available in or near staging area for the afternoon

Post-Inspection Tasks

Provide for prompt photocopying of the ISR Part B following the summation conference.

Remind laboratory staff that the documented responses, based on the ISR handwritten deficiencies, must be returned to CAP headquarters within 30 calendar days of the inspection.

Coordinate the return of deficiency response materials to CAP headquarters.
SITE COORDINATOR’S CHECK-OFF LIST
UNANNOUNCED INSPECTIONS

Preliminary Tasks

☐ Determine which functions the laboratory director has designated to the site coordinator.

☐ Make sure documentation of correction of deficiencies is complete:
  • From the last on-site inspection
  • From the self-evaluation

☐ Ensure complete reapplication submitted to the CAP by required date, including black-out dates and accurate test menus for all labs.

☐ Develop an unannounced inspection plan for when the one-hour security notification has been received, including (but not necessarily limited to):
  • What activities need to occur and who will do what
  • Who will be responsible for initiating the notification tree, and how notification will occur
  • Who will be working directly with the inspection team, including their phone and/or pager numbers
  • How meeting rooms will be arranged/secured for “home base” for the team, as well as preinspection and summation conferences
  • How meals/refreshments will be provided for the team
  • How to ensure that the telephone number provided for the one hour security call will have a person available to accept the call.
  • How transportation between facilities will be facilitated
  • How the medical staff representative and the representative from administration will be notified of the need to be available when the inspection team arrives, and how to develop a contingency plan if these individuals are not available.

To Be Accomplished Once the One-Hour Security Notice Has Been Received

☐ Initiate unannounced inspection plan.

☐ Alert medical director(s), site administrator(s), and lab personnel that inspection team has called, and what time they will arrive.

☐ Ensure that the team will be met and directed to the lab/conference room.

☐ Determine availability for meetings with:
  • Hospital administrator/chief executive officer
  • Chief of staff/chief medical officer
☐ Ensure personal protective equipment (PPE) is available for the team.

To Have Ready for the Inspection (in a location convenient to the laboratory)

☐ Centralized records, to be available throughout the course of the inspection
☐ Personnel files for all lab employees and other employees performing testing
☐ Department specific documentation and procedure manuals
☐ Supplies such as paper pads, pens, sticky notes/flags

Post-Inspection Tasks

☐ Provide for prompt photocopying of the ISR Part B following the summation conference.

☐ Remind laboratory staff that the documented responses, based on the ISR handwritten deficiencies, must be returned to CAP headquarters within 30 calendar days of the inspection.

☐ Coordinate the return of deficiency response materials to CAP headquarters.
Appendix G:
Retention of Laboratory Records and Materials

The College of American Pathologists (CAP) makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. These requirements meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The CAP urges laboratories to retain records and/or materials for a longer period of time than specified when such would be appropriate for patient care, education, or quality management needs. Some state regulations as well as other federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA regulations; therefore, individual laboratories should carefully review any applicable state or federal laws when they develop their record retention policies.

<table>
<thead>
<tr>
<th>MATERIAL/RECORD</th>
<th>PERIOD OF RETENTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Laboratory</strong></td>
<td></td>
</tr>
<tr>
<td>Accession log records</td>
<td>2 years</td>
</tr>
<tr>
<td>Maintenance/instrument maintenance</td>
<td>2 years</td>
</tr>
<tr>
<td>Quality control records</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Surgical Pathology (including bone marrow)</strong></td>
<td></td>
</tr>
<tr>
<td>Wet tissue</td>
<td>2 weeks after final report</td>
</tr>
<tr>
<td>Paraffin blocks</td>
<td>10 years</td>
</tr>
<tr>
<td>Slides</td>
<td>10 years</td>
</tr>
<tr>
<td>Reports</td>
<td>10 years</td>
</tr>
<tr>
<td><strong>Cytology</strong></td>
<td></td>
</tr>
<tr>
<td>Slides (negative-unsatisfactory)</td>
<td>5 years</td>
</tr>
<tr>
<td>Slides (suspicious-positive)</td>
<td>5 years</td>
</tr>
<tr>
<td>Fine-needle aspiration slides</td>
<td>10 years</td>
</tr>
<tr>
<td>Reports</td>
<td>10 years</td>
</tr>
<tr>
<td><strong>Nonforensic Autopsy</strong></td>
<td></td>
</tr>
<tr>
<td>Wet tissue</td>
<td>3 months after final report</td>
</tr>
<tr>
<td>Paraffin blocks</td>
<td>10 years</td>
</tr>
<tr>
<td>Slides</td>
<td>10 years</td>
</tr>
<tr>
<td>Reports</td>
<td>10 years</td>
</tr>
<tr>
<td>MATERIAL/RECORD</td>
<td>PERIOD OF RETENTION</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Forensic Autopsy</strong></td>
<td></td>
</tr>
<tr>
<td>Wet stock tissue</td>
<td>1 year</td>
</tr>
<tr>
<td>Paraffin blocks</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Reports</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Slides</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Gross photographs/negatives</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Accession log records</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Body fluids and tissues for toxicology</td>
<td>1 year</td>
</tr>
<tr>
<td>Representative tissue suitable for DNA analysis</td>
<td>Indefinitely</td>
</tr>
<tr>
<td><strong>Clinical Pathology Materials</strong></td>
<td></td>
</tr>
<tr>
<td>Patient test records</td>
<td>2 years</td>
</tr>
<tr>
<td>Serum/heparinized or EDTA plasma/CSF/</td>
<td></td>
</tr>
<tr>
<td>Body fluids (except urine)</td>
<td>48 hours</td>
</tr>
<tr>
<td>Urine</td>
<td>24 hours*</td>
</tr>
<tr>
<td>Peripheral blood smears/body fluid smears</td>
<td>7 days</td>
</tr>
<tr>
<td>Permanently stained slides—microbiology</td>
<td>7 days</td>
</tr>
<tr>
<td>(Gram, trichrome, etc)</td>
<td></td>
</tr>
<tr>
<td><em>Exceptions may be made at the discretion of the laboratory director.</em></td>
<td></td>
</tr>
<tr>
<td><strong>Cytogenetics</strong></td>
<td></td>
</tr>
<tr>
<td>Permanently stained slides</td>
<td>3 years</td>
</tr>
<tr>
<td>Fluorochrome-stained slides</td>
<td>At the discretion of the laboratory director</td>
</tr>
<tr>
<td>Wet specimen/tissue</td>
<td>Until adequate metaphase cells are obtained</td>
</tr>
<tr>
<td>Fixed-cell pellet</td>
<td>2 weeks after final report</td>
</tr>
<tr>
<td>Final reports</td>
<td>20 years</td>
</tr>
<tr>
<td>Diagnostic images (digitized, prints or negatives)</td>
<td>20 years</td>
</tr>
<tr>
<td><strong>Flow Cytometry</strong></td>
<td></td>
</tr>
<tr>
<td>Gated dot plots and histograms</td>
<td>10 years</td>
</tr>
<tr>
<td>MATERIAL/RECORD</td>
<td>PERIOD OF RETENTION</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Blood Bank</td>
<td></td>
</tr>
<tr>
<td>Donor records</td>
<td>10 years</td>
</tr>
<tr>
<td>Patient records</td>
<td>10 years</td>
</tr>
<tr>
<td>Records of employee signatures, initials, and identification codes</td>
<td>10 years</td>
</tr>
<tr>
<td>Quality control records</td>
<td>5 years</td>
</tr>
<tr>
<td>Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipients protection (eg, those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>Specimens from blood donors units and recipients</td>
<td>7 days post-transfusion</td>
</tr>
</tbody>
</table>
Appendix H: Glossary of Terms

Accepted PT Provider
A proficiency testing provider whose program has been determined by the CAP to be acceptable for use by CAP-accredited laboratories. Acceptance of PT providers is determined separately for each analyte.

Accreditation
The determination by the CAP that a laboratory has successfully met the Standards for Laboratory Accreditation of the College of American Pathologists’ Laboratory Accreditation Program (LAP).

Accreditation Checklist
A detailed series of requirements against which a laboratory is evaluated to determine compliance with the Standards for Laboratory Accreditation of the College of American Pathologists’ Laboratory Accreditation Program.

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

Accreditation Packet
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 With Requirements
Accreditation status assigned to a laboratory that is able to demonstrate compliance with all accreditation requirements; though during the review process, a need has been identified for an interim follow-up assessment to monitor ongoing compliance.

Activity
In the CAP accreditation programs, an activity is 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 nontest activities subject to inspection and accreditation.

Activity Menu, AU-Specific
The list of tests and nontest activities specific to an AU. The AU-specific activity menu is used to create the customized checklists, monitor PT, inspect, and report accreditation.
**Alternative Assessment**
The determination of laboratory testing performance by means other than proficiency testing (e.g., split-sample testing, testing by a different method, etc).

**Analyte-Specific Reagent (ASR):**
Antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. In contrast to reagents for in vitro diagnostic use, the FDA has not approved ASRs for use in human specimens.

**Analytic Measurement Range (AMR)**
The range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process.

**Analytic Measurement Range (AMR) Validation**
The process of confirming that the assay system will correctly recover the concentration or activity of the analyte over the AMR.

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

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

**Annual**
For the purpose of compliance with the checklist requirements, every twelve (12) calendar months.

**Application**
Forms completed by the laboratory to initiate the accreditation process.

**Appropriateness**
The extent to which a particular procedure, treatment, test or service is clinically effective, indicated, not excessive, adequate in quantity, and provided in the inpatient, outpatient, home or other setting best suited to the patient’s needs.

**AU**
See Accreditation Unit.
AU-specific Activity Menu
See Activity Menu, AU-specific.

Biennial
For the purpose of compliance with the checklist requirements, every twenty-four (24) calendar months.

Calibration
The set of operations that establish, under specified conditions, the relationship between reagent system/instrument response and the corresponding concentration/activity values of an analyte.

Calibration Verification
The process of confirming that the current calibration settings remain valid for a method.

Calibrator, historical
The set of archived results of a single-point calibrator that demonstrates stability of the assay over time.

CAP 15189
- CAP 15189 is a voluntary, nonregulated accreditation to the ISO 15189:2007 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 laboratories 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 programs which have met the CAP criteria for PT programs. Acceptance is by analyte only and should not infer the entire program.

The following definition will go into effect for the 2014 Proficiency Testing Program year.

For laboratories subject to US regulations, participation in proficiency testing may be through CAP PT Programs or another proficiency testing provider accepted by CAP.

For laboratories not subject to US regulations, participation in proficiency testing must be through CAP PT Programs. 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.

CDC
Centers for Disease Control and Prevention.
Change of Discipline Form
A form sent to an accreditation unit (AU) after it has indicated a change in services that create an additional discipline. The form comprises a list of activities pertinent to the added discipline. The AU indicates the activities in which it participates, so that they may be added to the AU-specific activity menu, as well as the volume of testing performed and supervision of the discipline. The regional commissioner will use this data to evaluate whether the discipline can be accredited without a nonroutine inspection.

Checklist, Custom
A checklist assigned to an individual laboratory which, based on its AU activity menu, includes only those requirements and groups of requirements that apply to the laboratory. In a customized checklist, some method-specific and analyte-specific groups of requirements—such as electrophoresis, factor assay, or sweat chloride—are not included when the AU does not perform those procedures.

Checklist
A detailed series of requirements designed to evaluate whether the laboratory 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. Each checklist item is classified by the CLA as Phase 0, Phase I, or Phase II. Failure to meet the requirements of a Phase II item may have a serious effect on patient care or worker safety; Phase I items are less serious. Phase 0 items do not require a formal response.

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 (Clinical Laboratory Improvement Act) Number
An ID number assigned to a laboratory by the CMS.

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, Center for Medicaid and Medicare Services due to the unique mission requirements within the DoD that are not found in the civilian sector.

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 these areas.

Clinical Validity
A test’s ability to detect or predict a disorder, prognostic risk, or other condition or to assist in the management of patients. The elements of clinical validity include, as applicable:

• Clinical sensitivity (clinical detection rate): the proportion of individuals with a disorder, prognostic risk, or condition that are detected by the test.

• Clinical specificity: the proportion of individuals without a disorder, prognostic risk, or condition that are excluded by the test.

• Reference limits: a value or range of values for an analyte that assist in clinical decision making. Reference values are generally of two types: reference intervals and clinical decision limits. A reference interval is the range of test values expected for a designated population of individuals. This may be the central 95% interval of the distribution of values from individuals who are presumed to be healthy (or normal). For some analytes that reflect high-prevalence conditions (such as cholesterol), significantly fewer than 95% of the population may be “healthy.” In this case, the reference interval may be something other than the central 95% of values. A clinical decision limit represents the lower or upper limit of a test value at which a specific clinical diagnosis is indicated or specified course of action is recommended.

• Clinical utility: the clinical usefulness of the test. The clinical utility is the net balance of risks and benefits associated with using a test in a specific clinical setting. Clinical utility does not take into consideration the economic cost or economic benefit of testing and is to be distinguished from cost-benefit and cost-effectiveness analysis. Clinical utility focuses entirely on the probabilities and magnitude of clinical benefit and clinical harm that result from using a test in a particular clinical context.

Note 1: The qualities listed above represent the primary performance measurements that are used to describe the clinical capabilities of a test. Other measures of clinical validity may be applicable in particular circumstances.

Note 2: Clinical validity is established in the context of a defined test population and a defined testing procedure. If the test population changes (eg, a change in the prevalence of disease) or the testing procedure changes, the clinical validity of a test may change.

Clinically Reportable Range (CRR)
The range of analyte values that a method can measure, allowing for specimen dilution, concentration, or other pretreatment used to extend the direct analytical measurement range (AMR).
CMS
Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration [HCFA]). 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)
A commission 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, and 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.

Commissioners, Special
Individuals responsible for special activities within the Commission on Laboratory Accreditation. Titles of Special Commissioners include: Accreditation Education Committee chair, Checklist Committee chair, Complaints Committee chair, Inspection Process Committee chair, Continuous Compliance Committee chair; special commissioner for systems; Forensic Drug Testing Accreditation Program commissioner; and Reproductive Laboratory Accreditation Program commissioner.

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.

Council on Accreditation
A council of the College of American Pathologists 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.

Critical PT Performance
Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for three consecutive or three of four consecutive testing events.
**Critical Result**
A test result that may require rapid clinical attention to avert significant patient morbidity or mortality.

**Custom Checklist**
See Checklist, Custom.

**Deemed Status**
The right granted by one organization to a second organization, that permits the second organization to determine if 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 if 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 AU must submit a plan of corrective action. For Phase II deficiencies, the AU must submit a plan of corrective action and supporting documentation showing that steps have been taken to correct the deficiency.

**De-identification**
Removal of health 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.

**Digital Image Analysis**
The computer-assisted detection or quantification of specific features in an image following enhancement and processing of that image, including immunohistochemistry, DNA analysis, morphometric analysis, and *in situ* hybridization.

**Director of Laboratory**
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.

**Discipline**
A CAP-defined term used to describe testing grouped within a major category of clinical laboratory science (eg, hematology, microbiology, and 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.

Examination
In the context of checklist requirements, examination refers to the process of inspection of tissues and samples prior to analysis. An examination is not an analytical test.

FDA
In the context of checklist requirements, FDA should be taken to mean the national, state, or provincial authority having jurisdiction over in vitro diagnostic test systems.

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)

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)

Final List of Deficiencies
A document included in the Accreditation Packet that lists deficiencies (if any), that were found during an Accreditation Unit’s accreditation inspection. The Final List of Deficiencies report does not include any deficiencies that were expunged.

Forensic Drug Testing (FDT)
The CAP accreditation program for laboratories that performs drug testing for nonmedical purposes (eg, workplace drug testing).

FDT
See Forensic Drug Testing.

General Supervisor
A position defined by CLIA 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
The 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.

IE
See Inspection Event.

II
See Inspection Instance.
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 Event (IE)
An identifier used within the CAP’s laboratory accreditation programs to determine appropriate checklists for inspections. For every AU cycle, there is one inspection event for every section unit.

Inspection Instance (II)
AUs and SUs grouped together for ease in the inspection (usually a single campus or geographic area).

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 materials sent to an inspection team leader to be used to conduct an inspection. Included are the appropriate number of checklists, laboratory synopsis reports, the Laboratory Accreditation Manual, Inspector Summation Report, etc.

Inspector’s Summation Report (ISR)
The form returned by the inspection team leader documenting inspection deficiencies and inspector’s comments.

IRC Laboratory
See Immediate Review Criteria.

Laboratory Inspection Packet
A packet of information sent to the laboratory prior to the on-site inspection that contains the AU-specific activity menu, response sheets, and instructions on how and when to respond to deficiencies.

Laboratory Developed Test (LDT)
A laboratory-developed test (LDT) is defined as follows: A test used in patient management that:

1. Either has all of the following characteristics:
   - The test is performed by the clinical laboratory in which the test was developed
   - The test is neither FDA-cleared nor FDA-approved, or is an FDA-cleared/approved test modified by the laboratory (sample types or the use of collection devices not listed in manufacturer instructions constitute modifications, by this definition)
   - The test was first used for clinical testing after April 23, 2003
2. Or is an FDA-cleared/approved test promoted by the laboratory for a use not approved by the FDA.

A laboratory is considered to have developed a test if the test procedure was created by the laboratory performing the testing, irrespective of whether fundamental research underlying the test was developed elsewhere or reagents, equipment, or technology integral to the test were purchased, adopted, or licensed from another entity.

**Laboratory Modified Test (LMT)**
An FDA-cleared or FDA-approved test that is modified by a clinical laboratory, but not to a degree that changes the stated purpose of the test, approved test population, or claims related to interpretation of results.

**License**
Right or permission granted in accordance with 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**
A CAP computer system-generated listing of the checklist requirements that were established as deficiencies at an inspection of a specific accreditation unit.

**Master Activity Menu**
See Activity Menu, Master.

**Medical Staff**
An organized group of physicians serving a health care institution that has overall responsibility for the quality of the professional services provided by its members with clinical privileges.

**Medical Technologist, Qualified**
An individual who is a graduate of a medical technology program approved by a nationally recognized body or who has the documented equivalent in education, training,
and/or experience; who meets current legal requirements of licensure or registration; and who is currently competent in the field.

**Method Performance Specifications**
The characteristics of a test that determine its ability to accurately and reliably measure the analyte (measurand) of interest. The term *analytic validity* may be used to refer these test characteristics. They include, as applicable:

**Accuracy**: The closeness of agreement between the average value obtained from a large series of measurements and the true value of the analyte.

Note: Technically, the term *accuracy* refers to the measure of the closeness of a single test result to the true value, not the average of multiple results. The definition of accuracy used here is what metrologists call “trueness of measurement” and describes to the popular (but technically incorrect) meaning of the word *accuracy*.

**Precision**: The closeness of agreement between independent results of measurements obtained under stipulated conditions. [IOS 1993]

**Reportable range**: For quantitative tests, the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response and over which results will be reported. For semiquantitative tests, the reportable range is all of the values that can be reported by the test system (eg, 2+, 3).

**Analytic sensitivity**: For quantitative tests analytic sensitivity is the lowest amount of analyte (measurand) in a sample that can be detected with (stated) probability, although perhaps not quantified as an exact value. For semiquantitative tests and qualitative tests (binary and nominal/categorical tests), analytic sensitivity is the lowest amount of analyte (measurand) in a sample that will cause a correct response.

**Analytic specificity**: Ability of a measurement procedure to measure solely the measurand/analyte.

Note: Method performance specifications are established in the context of a defined set of test conditions (including standard operating procedures and permissible specimen types) and an ongoing quality management regimen (including, as applicable, ongoing quality control, periodic assay recalibration, and external proficiency testing or alternative external testing). If the test conditions or quality management regimen changes, the method performance specifications of a test may change.

Additional note: CLIA includes reference range as a method performance specification, but the CAP treats reference range separately (see *Clinical Validity*).

**Moderate Complexity**
The rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health.
**Monitoring**
The systematic process of gathering and evaluating data so that problems or opportunities to improve care can be identified.

**Nonroutine Inspection**
Any on-site inspection performed in addition to the biennial routine on-site inspection. Nonroutine 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**
Tests categorized as either moderately complex (including provider-performed microscopy) or highly complex by the US Food and Drug Administration (FDA), according to a scoring system used by the FDA and according to CLIA.

**Pathologist**
A physician who 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) obtained from people.

**Pathology Service or Laboratory**
An activity, facility, or organization that provides services in the field of pathology.

**Physician**
An individual who has received a doctor of medicine or osteopathy degree and who is currently fully licensed to practice medicine.

**Physician Member of the Medical Staff**
A doctor of medicine or, osteopathy who, by virtue of clinical privileges granted by the institution, is permitted to perform specific diagnostic or therapeutic procedures.

**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.

**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 laboratories 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.

**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 or 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.

**Proficiency Testing (PT) (Also termed: External Quality Assessment [EQA])**
The determination of laboratory testing performance by means of inter-laboratory 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 Compliance Notice (PTCN) – Enrollment**
A notification packet is sent to the laboratory indicating that the CAP has not received enrollment data for the activities the laboratory listed on its menu.

**Proficiency Testing Compliance Notice (PTCN) – Nonparticipation**
A notification packet that is sent to a laboratory when a laboratory indicates on its CAP activity menu that a test is performed and the laboratory has enrolled in an appropriate
PT product(s) but the CAP did not receive a score from the PT provider. Nonparticipation monitoring is a continuous process.

**Proficiency Testing Compliance Notice (PTCN) – Performance**
A notification packet that is sent to the laboratory when a laboratory receives an unsatisfactory (first-time event) or unsuccessful (multiple events) PT score. Performance monitoring is a continuous process.

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

**Quality**
The totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs.

**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 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 (QM)**
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.

**Reagent**
Any substance in a test system other than a solvent or support material that is required for the target analyte to be detected and its value measured in a sample.

**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.

**Reference Laboratory or Referral Laboratory**
The laboratory that receives a specimen for analysis from another laboratory.

**Regulated Analyte**
A test for which the CLIA regulations require participation in proficiency testing.

**Reproductive Laboratory Accreditation Program (RLAP)**
The CAP accreditation program that accredits laboratories that perform andrology and embryology testing.

**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.

**Scientific Director**
A lab-appointed director associated with an AU (FDT only).

**Section Unit (SU)**
An operational area or department of an AU, 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.

**Semiannual**
For the purpose of compliance with the checklist requirements, every six (6) calendar months.
Sentinel Checklist Item
An accreditation checklist item that, if cited, indicates a significant probability of other significant checklist deficiencies or a significant risk to patient safety.

Single-Use Device (also termed: Unit-Use device)
A testing system in which reagents, calibrators and wash solutions (and, in some cases, electronics such as sensors) are packaged in a single container, without reuse of reagents, calibrators, or wash solutions from test to test. The container is discarded after each test (adapted from CLSI EP-18-A).

Special Function Laboratory
Any laboratory not under the direct jurisdiction of the director of 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) who conducts inspections on behalf of the CAP.

Standards
The Standards for Laboratory Accreditation as published by the Council on Accreditation of the College of American Pathologists. 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.

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

Suspension
Removal of accreditation of 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, or doctoral scientist and must be qualified to direct a high complexity laboratory under CLIA.

**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, or other physician, or a doctoral scientist and must be qualified to direct a high complexity laboratory under CLIA.

**Telepathology**
The practice in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or document in the patient record.

**Termination**
The process by which a laboratory’s accreditation is ended and all regulatory agencies involved with the laboratory are notified. The reasons for termination include:
- Denial of an accreditation unit’s accreditation after an inspection.
- Initiation of termination by the AU itself when it no longer wishes to participate in the CAP’s laboratory accreditation programs. The AU is responsible for notifying CAP staff of its intention to discontinue coverage under the CAP’s laboratory accreditation programs.
- Failure to return reapplication materials within a specified time frame. The termination will occur after reminder options (additional documentation) have been exhausted. Letters will be sent to the AU and the regional commissioner stating that the laboratory has been terminated because reapplication materials were not received.
- Merger of two or more AUs, which results in the accreditation of a single AU. The AUs that are no longer effective will be terminated and the surviving AU’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**
As performed in a clinical laboratory, a test is an analysis of specimens such as blood or urine that typically yields a clinical result, used either to diagnose illness or to aid in treatment.

**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. (See *Waived Tests*.)
Test System
The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or singl-use, and can include reagents components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

Unsatisfactory Proficiency Testing Performance
Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful Proficiency Testing Performance
Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or for two consecutive or two of three consecutive testing events (See also Unsatisfactory Proficiency Testing Performance.). Usually, a laboratory that demonstrates unsuccessful performance for an analyte or discipline must cease testing for that analyte or that discipline.

Validation of a Test
Confirmation through a defined process that a test performs as intended or claimed.

Note: There is no universally acceptable procedure for validating tests. The process for validating tests must take into account the purpose for which a test is intended to be used, claims made about the test, and the risks that may prevent the test from serving its intended purpose or meeting performance claims. Even FDA-approved and FDA-cleared tests require limited revalidation in clinical laboratories (a process often referred to as verification) to establish that local implementation of the test can reproduce a manufacturer’s validated claims. Tests that use reagents or equipment that have not been validated typically pose increased risks that require more extensive validation, as do tests used in more loosely controlled settings. The determination of whether a test has been adequately validated requires professional judgment.

Verification of a Test
An abbreviated process through which a clinical laboratory establishes that its implementation of an FDA-approved and FDA-cleared test performs in substantial conformance to a manufacturer’s stated claims.

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 Tests
A category of tests defined by CLIA 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 I:
Accreditation Requirements When a PT Result Is Linked to an Exception Reason Code

The College uses exception reason codes to signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. The laboratory must identify all of the analytes with an exception reason code and investigate the acceptability of its performance with the same rigor as if it were an unacceptable performance.

Whenever an exception reason code is present, review the all-participant statistics for any explanatory information. The actions accredited laboratories should take include but are not limited to:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Exception Reason Code Description</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Unable to analyze</td>
<td>Document why the specimens were not analyzed (eg, instrument not functioning or reagents not available). Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.</td>
</tr>
<tr>
<td>20</td>
<td>No appropriate target/response; cannot be graded</td>
<td>Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, all method, or all participant statistics if provided. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.</td>
</tr>
<tr>
<td>21</td>
<td>Specimen Problem</td>
<td>Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary. Perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested. Credit is not awarded in these cases.</td>
</tr>
<tr>
<td>22</td>
<td>Result is outside the method/instrument reportable range</td>
<td>Document the comparison of results to the proper statistics supplied in the Participant Summary. Verify detection limits.</td>
</tr>
<tr>
<td>24</td>
<td>Incorrect response due to failure to provide a valid response code</td>
<td>Document the laboratory’s self-evaluation against the proper statistics and evaluation criteria supplied in the Participant Summary. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.</td>
</tr>
<tr>
<td>25</td>
<td>Inappropriate use of antimicrobial</td>
<td>Document the investigation of the result as if they were unacceptable and review the proper reference documents to gain knowledge of the reason your response is not appropriate.</td>
</tr>
<tr>
<td></td>
<td>Educational Challenge</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>26</td>
<td>Response to the CAP is not required. Laboratory should document its review.</td>
<td></td>
</tr>
<tr>
<td>27,31</td>
<td>Lack of participant or referee consensus</td>
<td>Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the Participant Summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached nonconsensus to the same level and extent that would have been tested.</td>
</tr>
<tr>
<td>28</td>
<td>Response qualified with a greater than or less than sign; unable to quantitate</td>
<td>Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the Participant Summary. Verify detection limits.</td>
</tr>
<tr>
<td>30</td>
<td>Scientific Committee Decision</td>
<td>Document that the laboratory has reviewed the proper statistics supplied in the Participant Summary.</td>
</tr>
<tr>
<td>33</td>
<td>Specimen determined to be unsatisfactory after contacting the CAP</td>
<td>Document that the laboratory has contacted the CAP and no replacements specimens were available. Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.</td>
</tr>
<tr>
<td>40</td>
<td>Results for this kit were not received</td>
<td>Document why results were not received, corrective action to prevent recurrence and the laboratory’s self-evaluation of the results by comparing results to the proper statistics and evaluation criteria supplied in the Participant Summary. If PT specimens were not analyzed, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.</td>
</tr>
<tr>
<td>41</td>
<td>Results for this kit were received past the evaluation cut-off date</td>
<td>The Participant Summary indicates which tests are graded (see evaluation criteria) and which tests are not evaluated/educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. The code 42 that appears on the evaluation is not a penalty. However, if a test is graded (regulated and nonregulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for all challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the kit instructions and/or the result form. Document corrective actions to prevent future failures.</td>
</tr>
<tr>
<td>42</td>
<td>No credit assigned due to absence of response</td>
<td>Verify that the drug is not tested on patient samples and document to ensure proper future reporting.</td>
</tr>
<tr>
<td>44</td>
<td>This drug is not included in our test menu. Use of this code counts as a correct response</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Action</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>45</td>
<td>Antimicrobial agent is likely ineffective for this organism or site of infection</td>
<td>Document that the laboratory performed a self-evaluation of written protocols and practices for routine reporting of antimicrobial susceptibility reports to patient medical records. Document that routine reporting of this result to clinicians for patient care is compliant with specific recommendations of relevant medical staff and committees (eg, infectious diseases, pharmacy and therapeutics, infection control). Response to the CAP is not required.</td>
</tr>
<tr>
<td>77</td>
<td>Improper use of the exception code for this mailing</td>
<td>Document the identification of the correct code to use for future mailings.</td>
</tr>
<tr>
<td>91</td>
<td>There was an insufficient number of contributing challenges to establish a composite grade</td>
<td>Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.</td>
</tr>
<tr>
<td>35, 43, 88, 92</td>
<td>Various codes</td>
<td>No action required.</td>
</tr>
</tbody>
</table>

03-2011
Appendix J:
Team Leader Inspection Planner

Complete each item listed below

1. Arrange the inspection
   • Do not contact the laboratory if this is an unannounced inspection. If this is an announced inspection, contact the laboratory director to set an inspection date.
   • Begin to select your team, including the number and types of inspectors needed. For instance, one inspector for the Laboratory General Checklist and one for the following checklist combinations: hematology and Urinalysis Checklists; Microbiology and Immunology Checklists; and Anatomic Pathology and Cytopathology Checklists. The Transfusion Medicine Checklist can be combined with another checklist (such as the Immunology Checklist or Point-of-Care Checklist) if the laboratory does not have a donor center.
   • If the laboratory is performing cytogenetics, flow cytometry, histocompatibility, or molecular pathology, a list of qualified inspectors within your geographic region is provided in the inspection packet and must be used. Please contact potential inspectors directly to determine availability. Contact Jennifer Williams, the inspector database specialist (800-323-4040 ext. 7380), if you need the names of additional qualified inspectors. The selected inspector should have specialty expertise and be actively involved in the discipline.
   • If there is a cytopathology inspection, the inspector must be a pathologist or cytotechnologist who is actively involved with cytopathology. Several hours should be allotted to allow enough time for a detailed slide review, direct observation of technical procedures, and a careful review of quality improvement monitors.
   • Identify all team members and gain commitments from them.

2. When the inspection packet arrives, review the contents immediately.
   • Verify the number and location of laboratories to be inspected.
   • Verify the checklists to be used for the inspection.
   • Review activity menus and instrumentation lists; determine skill sets necessary for team members.
   • Confirm commitment of all team members.
   • If you have not already done so, contact the CAP and report the planned inspection date, total number of inspectors, and the total number of days the inspection will be occurring.
   • Call CAP Travel Office (800-323-4040 ext. 7800) to make travel and/or hotel arrangements for the team, if necessary, and complete the travel request form. If air travel is required, arrangements must be made through the CAP Travel Desk. Hotel reservations must be made through the CAP Travel Desk if more than 10 total hotel nights are being booked for the team. To ensure the best availability of airfare and hotel choices, whenever possible, please contact the Travel Desk at least one month prior to travel.
3. Prepare the team
   • Meet with the inspection team at least one week prior to the inspection.
   • Distribute section and checklist-specific packets and discuss travel arrangements, inspection conduct, timing, etc. This can be done by conference call if a face-to-face meeting cannot be arranged.
   • Discuss with team members the importance of familiarizing themselves with the materials specific for their inspection responsibilities.
   • Ensure you and your team members have completed inspector training that is available at no cost.
     o Visit the CAP website (http://cap.org),
     o click on Education Programs,
     o Select Accreditation Education Activities
     o Choose Inspector Training and select the appropriate subcategory
     o Direct any education question to 800-323-4040 option 1.

4. During the inspection
   • For security purposes, one hour prior to your arrival, please call the laboratory to announce your intent to inspect.
   • Arrive on time. Inspections of full-service laboratories typically begin before 8:00 AM and conclude between 4:00–6:00 PM. Be sure to allow adequate time for a thorough inspection.
   • Some labs may require a photo ID to gain entrance on the day of the inspection. Be sure you and your team members have adequate identification (driver’s license, state ID, passport). Passports are required for travel to Canada and Mexico.
   • Present the inspection announcement letter to the ab director or designee.
   • Introduce the team to the laboratory personnel with whom each will be working.
   • Discuss arrangements for lunch, summation conference, interviews for the team leader, working area for the team, etc.
   • Remind team to discuss all deficiencies with the supervisor/laboratory representative as they are identified and summarize them at the end of the section inspection.
   • Maintain contact with the team during the day (eg, brief midmorning meeting, working lunch, etc) to verify progress, answer questions, and redirect resources if necessary.
   • Call the CAP at 800-323-4040 during the day of the inspection if there are questions that the team cannot answer.

5. Presummation
   • Meet with the inspection team prior to the summation conference to discuss all deficiencies, answer team members’ questions, and establish consistency.
   • Remind your team to complete the deficiency and recommendations forms as follows:
     o Complete forms prior to summation conference.
     o For each citation, enter the requirement ID and the specific reason the laboratory is deficient.
     o Print name and credential and sign and date each Inspector Summation Report (ISR) page.
6. **Summation conference**
   - Discuss *all* deficiencies and recommendations and suggest potential corrective action strategies.
   - Obtain the laboratory director’s signature on page 3 of Part A of the ISR.
   - Leave a copy of the Deficiencies and Recommendations forms with the laboratory.
   - Give the envelope with deficiency response instructions and forms to laboratory personnel.
   - Remind laboratory personnel that they have 30 days to respond to all deficiencies. Explain how to respond to both Phase I and Phase II deficiencies.

7. **After the inspection**
   - Complete page 1 of Part A of the ISR, and note comments on page 2.
   - Return the complete ISR within 24 hours using the prepaid Express mailer in the packet. This would include pages 1–3 of Part A, *all* deficiency and recommendation pages (even those that were unused), and the ISR index page.
   - Collect Team Leader/Member Evaluation forms and expense receipts, fill out reimbursement form, and mail to CAP headquarters. Provide the address for the reimbursement check, and sign the reimbursement form. Accounts Payable cannot issue checks without the signature of the inspector to be reimbursed.
   - Discard checklists and any other information regarding the inspection.
Appendix K: Team Member Inspection Planner

Complete each item listed below

**Do not contact the laboratory director or any member of the laboratory staff regarding this inspection.**

1. **Complete the required Team Member Inspector Training**
   - Access the CAP website (http://cap.org), click on “Education Programs,” then select “Accreditation Education Activities” to review training options.
   - Click on “Inspector Training (fulfills training requirement)” and select the appropriate subcategory.
   - Inspection training is available to team members at no cost.
   - Training must be completed within the two years prior to the inspection.
   - Direct any education questions to 800-323-4040 ext. 7525 or education@cap.org.

2. **Obtain a copy of the Laboratory Accreditation Manual from the team leader or online at http://cap.org. Review the following pertinent sections:**
   - Definitions of Phase I and Phase II deficiencies
   - Commission Philosophies
   - Conducting the Inspection; General Principles and Meetings
   - Inspecting the Laboratory Sections (general guidelines for each checklist); review your particular section and Requirements Applicable to All Laboratory Sections
   - The Summation Conference

3. **Review your inspection materials prior to the inspection date. Each checklist should have these related items:**
   - Section Synopsis Report
   - Instrumentation list
   - Proficiency Testing Performance Report
   - Team Member Evaluation
   
   **Each checklist packet should have:**
   - Deficiency (pink) and Recommendations (yellow) forms
   - AU Activity Menu (list of procedures and analytes)
   - Inspector Summation Report from previous inspection
   - Checklist
   
   **Inspection packet should also contain:**
   - Name tag (wear at all times during the inspection).
   - Team Member Evaluation form (complete after inspection and return to the CAP).
   - Reimbursement form (if travel is involved). Provide the address for the reimbursement check, and sign the reimbursement form. Accounts payable cannot issue checks without the signature of the inspector to be reimbursed.

4. **Examine inspection materials carefully prior to the inspection date to ensure that you are familiar with the checklist version used and the procedures/analytes to be inspected. Other ways to prepare include:**
- Be sure that you feel qualified to carry out the inspection(s) assigned. Discuss any questions with the inspection team leader prior to the inspection.
- If you have questions about interpretation of checklist items, email a question to the CAP at accred@cap.org, or phone 847-832-7000 or 800-323-4040.
- Perform a mock inspection of your own laboratory using the checklist provided.

5. During the inspection:
   - Arrive on time.
   - Maintain a professional attitude at all times.
   - If inspecting more than one section, develop a schedule with the section supervisors.
   - For each section, review documentation and observe actual testing.
   - Review deficiencies cited at the last on-site inspection, paying particular attention to recurring deficiencies. Ensure that the laboratory is following the procedures or processes that are appropriate to meet the College’s standards set forth in the Standards for Laboratory Accreditation.
   - Discuss all deficiencies with the supervisor/laboratory representative as they are identified, and summarize them at the end of the section inspection.
   - During lunchtime, inform the team leader of your progress.
   - If uncertain about the interpretation of a checklist requirement, discuss with the team leader. If still uncertain, call CAP headquarters at 800-323-4040.

6. At the presummation conference:
   - Discuss all deficiencies with the team leader. Warn the team leader if there has been a disagreement over a checklist item with the supervisor.
   - Write deficiencies on the appropriate deficiency (pink) page for each checklist. For each citation, record the requirement ID and the specific reason the laboratory is deficient. If no deficiencies, check the “This lab section had no deficiencies” box at the top of the page.
   - Write recommendations on the appropriate Recommendations (yellow) page for each checklist. Recommendations need not relate to a specific checklist requirement
   - Print and sign your name in the bottom section of each Deficiencies and Recommendations page.

7. When presenting your findings at the summation conference:
   - Thank the supervisor that you worked with by name.
   - Findings include both positive and negative observations. Compliments for good work set a favorable tone.
   - Present deficiencies in a straightforward manner. Do not intermix recommendations with deficiencies. Supply deficiency corrective action strategies to the laboratory supervisors and staff members.
   - If the lab personnel disagree with a citation, listen carefully to their explanation, but do not get into an argument. If you continue to believe your finding is a deficiency, the lab can provide documentation to the CAP as to why it believes it is in compliance. The CAP will decide which interpretation is correct.
   - Return Deficiencies and Recommendations forms to the team leader for collation and copying. Return even if not used.
Don’t be in a rush to leave immediately after the summation conference. If you have performed your job with fairness and respect, there are usually good feelings to be shared at the end of the day.
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College of American Pathologists Laboratory Accreditation Program Policies (May 2011)

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1. ACCREDITATION

1.01 Requirements for Accreditation

1.01.a.1. To be considered for accreditation by the CAP accreditation programs, a laboratory must submit an appropriately completed application and necessary deposits or fees.

1.01.a.2. To be accredited by the CAP accreditation programs, a laboratory must be judged by the Commission on Laboratory Accreditation to be in compliance with the Standards for Laboratory Accreditation, the Standards for Reproductive Laboratory Accreditation, the Standards for Forensic Drug Testing Laboratory Accreditation, or the Standards for Biorepository Accreditation, whichever is applicable.

1.01.b. For each two-year accreditation period (for laboratory accreditation) or each three-year accreditation period (for biorepository accreditation), a laboratory must provide a trained inspection team of a size and composition similar to that required for its own inspection, if requested to do so by the assigning commissioner.

1.01.c.1. Laboratories located outside the United States, Mexico and Canada will be required to pay round trip business class airfare(s) for inspector(s), at the discretion of the chair of the commission, in addition to any ordinary accreditation fees, if it is necessary to assign an inspector from another country.

1.01.c.2. Laboratories located within the United States, Mexico and Canada will not be required to pay travel expenses for inspector(s).

1.01.d.1. A laboratory must submit to a complete inspection. For laboratories subject to CLIA, the CAP will inspect and accredit all testing performed under the laboratory’s CLIA number that generates results used in or directly impacting patient care. This includes tests used in the diagnosis and treatment of patients in clinical trials. For laboratories performing testing or activities not subject to CLIA, the CAP will inspect and accredit all of the non-CLIA testing or activities in the laboratory under the same director, same laboratory name, and same address. For any laboratory located outside of the United States and not subject to CLIA, the CAP will inspect and accredit all testing or activities performed by the laboratory. Exceptions may be made based on circumstances.

1.01.d.2. If a laboratory fails to identify any test or testing site under its CLIA number, the commission may elect to conduct a non-routine inspection of the test or testing site at the laboratory’s expense. If a laboratory not subject to CLIA fails to identify any testing or activities under the same director, same laboratory name, and same address, the commission may elect to conduct a non-routine inspection of the testing or activities at the laboratory’s expense.

1.02 Accreditation Fees

1.02.a. Fees for participation in the CAP accreditation programs shall apply annually.

1.02.b. Appropriate fees shall be assessed for inspections that result in accreditation denial.

1.02.c. Additional fees may be assessed for non-routine inspections.
1.02.d. Accreditation fees are non-refundable.

1.02.e. Alternative fee schedules may be defined by contractual arrangement.

**1.03 Participation in Proficiency Testing**

1.03.a.1. The Commission on Laboratory Accreditation through the Continuous Compliance Committee will determine which analytes or methods require proficiency testing (PT). The decision will be based on the availability of appropriate testing materials and the value of participation in the PT program. CAP-accredited laboratories must participate in a CAP-accepted PT program for all such analytes or methods on the laboratory activity menu. Exceptions for special circumstances may be adjudicated by the Continuous Compliance Committee.

1.03.a.2. CAP-accredited laboratories subject to US regulations must participate in either the CAP Proficiency Testing Programs or a CAP-accepted PT program.

1.03.a.3. CAP-accredited laboratories not subject to US regulations must participate in the CAP Proficiency Testing Programs.

1.03.a.4. CAP-accredited laboratories must develop an acceptable plan to assess performance, at least semi-annually, for analytes or methods not on the list of required analytes or methods or for analytes or methods for which CAP-accredited laboratories are unable to enroll in either the CAP Proficiency Testing Programs or a CAP-accepted PT program due to special circumstances acknowledged by the Continuous Compliance Committee. Such a plan might include using a commercially available PT product, split sampling with another laboratory, split sampling with another method, chart review, or other method as approved by the laboratory director.

1.03.b. When an accredited laboratory fails to demonstrate proficiency, as defined by the commission, the laboratory must, on a timely basis and if requested, submit, for review by the commission, appropriate documentation of its investigation of the cause of the unacceptable performance and of corrective actions taken, if any.

1.03.c.1. When an accredited laboratory demonstrates recurrent unsatisfactory (unsuccessful or critical*) performance in PT for an analyte, a subspecialty or a specialty, the commission may, as it deems necessary, or as required under the CLIA regulations, impose sanctions which can include a directive to cease testing to ensure that the laboratory corrects the underlying problems and performs the tests in a manner that will not jeopardize patient safety.

*Unsuccessful performance is unsatisfactory performance in two out of three events of PT. Critical performance is unsatisfactory performance in three out of four events.

1.03.c.2. When an accredited laboratory receives a directive to cease testing from the Continuous Compliance Committee and fails to comply with the requirements of the directive, the laboratory may be referred to the Accreditation Committee. The Accreditation Committee may impose sanctions on the laboratory which can include denial or revocation of accreditation.
1.04 Accreditation Checklists

1.04.a.1. The Checklist Committee of the Commission on Laboratory Accreditation is responsible for the development and maintenance of the checklists.

1.04.a.2. The Checklist Committee obtains technical consultation for the checklists from the various resource committees.

1.04.b. Checklists are used by the commission and inspectors to evaluate a laboratory’s compliance with the governing Standards for Accreditation.

1.04.c. Except to the extent permitted by the fair use provisions of the Copyright Act, any entity that wishes to reprint or translate all or any part of any checklist or to incorporate all or any part of any checklist into any other work must first enter into a Checklist License Agreement by which the entity (a) acknowledges and agrees to respect the CAP's copyright in the checklist, (b) agrees to make no deceptive claims with respect to its use of the checklists or its relationship with the CAP, and (c) accepts such other conditions, including the payment of a royalty, as may be required by the commission.

1.05 Release of Accreditation Information

1.05.a.1. Except as noted in sections 1.05.a.2, 1.05.d and 1.17.c.2, the only information about an inspected laboratory that can be released is its current accreditation status, the date of its last on-site inspection, its accreditation status on any given date, and the date of its first accreditation continuous with the current accreditation.

1.05.a.1.1. Other than as specified in this section and in sections 1.05.a.2, 1.05.d and 1.17.c.2, any information or material received by the CAP in connection with an inspected laboratory’s participation in the CAP accreditation programs is considered confidential and will not be released unless release is authorized by the director or is required by law.

1.05.a.2. Responses to inquiries concerning CAP accreditation programs will be based on printed information, written committee policies and procedures, published data summaries and program specifications.

1.05.a.2. If the Commission on Laboratory Accreditation at any time learns of any laboratory practices that appear to be unlawful or unethical or that might pose significant risk to patients or laboratory personnel, the commission may disclose such information, as it deems appropriate – even without authorization from the director.

1.05.a.3. The CAP will publish a laboratory’s current accreditation status on the CAP website for public access. The CAP will not disclose inspection reports, but instead, will refer inquiries to the laboratory in question.

1.05.b. Except as provided for in 1.05.a.2, 1.05.d and 1.17.c.2, the CAP shall not release specific information about a laboratory to agencies or organizations outside the CAP without the written authorization of the director or other appropriately authorized individual.

1.05.c. Internal documents relating to aggregate laboratory performance within the CAP accreditation programs shall not be released to agencies, organizations, or individuals outside the CAP without authorization from the chair of the commission (or designee).
1.05.d.1. If a laboratory is using CAP accreditation to meet the licensing requirements as required by regulations deriving from CLIA'88, the CAP will release such documents to the Centers for Medicare and Medicaid Services as required by federal regulation or law.

1.05.d.2. If a laboratory is using CAP accreditation for purposes of the Joint Commission accreditation in an institution accredited by it, the CAP will release to the Joint Commission such documents as are required by any agreements between the two organizations.

1.05.d.3. If a laboratory is using CAP accreditation to meet licensing requirements of any state that has granted sub-deeming authority to the CAP, the CAP will release to the state such documents to that state as are required under terms of the agreement, regulations granting sub-deeming authority, or as otherwise required by law or regulation.

1.05.e. The CAP will release specific inspection and accreditation information regarding all accredited laboratories within a system to the system contact and/or other designated contact of that system.

1.05.f. The CAP will, upon request, release specific inspection and accreditation information regarding all accredited laboratories within an institution to the chief executive officer of that institution.

1.06 News Media Inquiries

1.06. All news media inquiries regarding the CAP accreditation programs or accredited laboratories must be forwarded to the senior vice president, Laboratory Improvement Programs, (or designee) as soon as possible.

1.07 Correction of Deficiencies

1.07.a.1. The laboratory must correct all deficiencies (phase I and phase II) within thirty days following the routine onsite inspection. For phase II deficiencies, the documentation of the correction must be provided.

1.07.a.2. Notwithstanding paragraph 1.07.a.1, the Accreditation Committee may specify a shorter time period for the laboratory to submit written responses to all deficiencies and to substantiate correction of phase II deficiencies cited.

1.07.a.3. A laboratory wishing to challenge a deficiency must submit a written statement explaining the basis for the position that it was in compliance at the time of the inspection. Such statements must be signed by the laboratory director and accompanied by supporting documentation. Challenges will be accepted only at the time that initial responses to deficiencies are submitted.

1.07.a.4. Documented evidence of plans to correct phase II space limitations (such as relocation or construction) must be submitted in writing to the reviewing commissioner. Substantial progress on plans to correct space limitations (such as relocation or construction) will be evaluated at the next inspection.
1.07.b. The reviewing commissioner may recommend to the Accreditation Committee that a laboratory i) be granted accreditation (policy 1.01) or preliminary accreditation (1.25), ii) be placed on probation (1.21) or accreditation with requirements (1.09), or iii) have accreditation be denied/revoked (1.08). The recommendation should be based on an evaluation of the number, nature, and persistence of deficiencies and an assessment of the likely effect of those deficiencies upon patient or facility safety, performance, and quality.

1.07.c. The reviewing commissioner may reclassify an inspection recommendation as a deficiency when it appears that the laboratory was out of compliance with an applicable requirement. In addition, the reviewing commissioner may request information and/or documentation regarding the inspection recommendation.

1.07.d.1. The Accreditation Committee or reviewing commissioner may, for the reasons stated in this subparagraph, determine that a facility is out of compliance with checklist requirements not specifically cited at the time of inspection. In that event, the committee or reviewing commissioner shall add the newly identified deficiencies to the Inspector’s Summation Report. A determination of noncompliance with checklist requirements pursuant to this subparagraph may be based on, but not limited to, review of the Inspector’s Summation Report Part A section, interview with the team leader or team member after the inspection, or review of the documentation provided in response to deficiencies cited at the time of inspection.

1.07.d.2. The director shall be notified in writing of the added deficiencies, and the laboratory must provide a written response to these deficiencies in accordance with paragraph 1.07.a.1-4.

1.08 Revocation/Denial of Accreditation

1.08.a.1. The Accreditation Committee of the Council on Accreditation may deny or revoke accreditation of a laboratory when it fails to meet the governing Standards for Accreditation of the CAP accreditation programs or when the laboratory fails to comply with the policies and procedures of the CAP accreditation programs. Denial of accreditation applies to laboratories seeking initial accreditation. Revocation applies to currently accredited laboratories.

1.08.a.2. A laboratory whose accreditation is denied or revoked shall be notified by express delivery, signature required.

1.08.a.3. All accreditation denials and revocations will be reported within the appropriate specified time frame to appropriate oversight agencies.

1.08.b.1. A laboratory whose accreditation has been denied or revoked by the Accreditation Committee may seek reconsideration by the Accreditation Committee within thirty days after notification of the accreditation decision based on the date of the notification letter (i.e., not the date the letter is received by the laboratory). A laboratory seeking reconsideration of a decision must submit documents supporting its position, preferably electronically. Furthermore, the director of the laboratory may be asked to participate in a conference call to explain its request.

1.08.b.2. In the event that the Accreditation Committee reaffirms its decision, a laboratory whose accreditation has been denied or revoked by the Accreditation Committee may appeal the decision to the council within thirty days after notification of the reaffirmation based on the
date of the notification letter (i.e. not the date the letter is received by the laboratory).

1.08.b.3. The council shall consider a properly filed appeal within thirty days following receipt of the appeal.

1.08.b.4. The council shall review each appeal and make a determination whether to invite representatives of the laboratory, at their expense, to appear before the council, in person or via conference call, to present and clarify relevant facts and to answer questions posed by the council members. This determination shall be conveyed to the laboratory within 10 days following review of the appeal.

1.08.b.5. The council shall act on any appeal at the meeting at which the appeal is heard unless the council determines that it requires additional information. If the council requests additional information, it shall decide the appeal at its next regularly scheduled meeting.

1.08.b.6. The decision of the council on an appeal shall be conveyed to the laboratory promptly after the decision is made.

1.08.b.7. Neither request for reconsideration by the Accreditation Committee nor appeal to the council shall stay the denial or revocation of accreditation.

1.08.b.8. If the denial or revocation of accreditation is overturned on reconsideration or appeal, the laboratory will be reinstated as of the time of the reversal, and the appropriate oversight agencies will be notified of the decision.

1.08.c.1. A laboratory whose accreditation has been denied or revoked may not apply for accreditation until six months have elapsed, based on the date of the notification of denial or revocation.

1.08.c.2. A laboratory whose accreditation has been denied or revoked and that has chosen to reapply for accreditation will be assessed fees equal to those fees assessed for a new application.

**1.09 Accreditation With Requirements**

1.09. The CAP accreditation programs, including the Commission on Laboratory Accreditation, its committees and reviewing commissioners, shall recommend accreditation with specific requirements, as appropriate, to the Accreditation Committee for approval. Furthermore, the Accreditation Committee shall also determine accreditation with specific requirements as appropriate.

**1.10 Terms of Accreditation**

1.10.a. The accreditation of a laboratory is valid until the next accreditation decision, unless otherwise specified as provided for in 1.09.

1.10.b. If a reviewing commissioner is unable to make an accreditation decision in a timely manner, the laboratory remains accredited until that decision has been made.

**1.11 Lapse of Accreditation**
1.11.a Unless the Commission on Laboratory Accreditation finds that there are extenuating circumstances, a laboratory’s accreditation will lapse on its anniversary date if it has not submitted a complete application for re-inspection on a timely basis, at least six months prior to its anniversary date.

1.11.a.1. If a laboratory fails to submit a reapplication on a timely basis and is using CAP accreditation for purposes of CLIA certification, the laboratory’s accreditation will lapse on its anniversary date and the Centers for Medicare and Medicaid Services will be notified.

1.11.a.2. If a laboratory fails to submit a reapplication on a timely basis and is using CAP accreditation to satisfy Joint Commission accreditation requirements, the laboratory’s accreditation will lapse on its anniversary date, and the Joint Commission will be notified.

1.11.a.3. If a laboratory fails to submit a reapplication on a timely basis and is using CAP accreditation for purposes of state licensure, the laboratory’s accreditation will lapse on its anniversary date and the state will be notified.

1.11.b. Refusal to provide an inspection team of a size and composition similar to that required for its own inspection, or a team leader, or appropriate team members if unable to provide a team leader, may result in non-renewal of the laboratory’s accreditation on its anniversary date, at the discretion of the commission.

1.11.c. The CAP will not accept or process an application or reapplication for accreditation, will not schedule an onsite inspection, and will not accredit any laboratory that has not paid in full its annual accreditation fee or other accreditation-associated charges (e.g. charges for international travel or non-routine inspections). Failure to pay for proficiency testing materials is not considered to be failure to pay accreditation-associated charges.

1.12 Change of Director

1.12.a. Accreditation by the CAP does not automatically continue upon any change of permanent, interim or acting director.

1.12.b. A laboratory must notify the CAP accreditation programs in writing within at least 30 calendar days prior to, or if unexpected, no longer than two working days after it undergoes a change of director. The notification must include a copy of the new director’s curriculum vitae, an organizational chart indicating the director’s position in the laboratory and within the institution, completed documentation of the director’s qualifications and responsibilities, and additional information as requested by the CAP.

1.12.c.1. Upon a change of director, the laboratory may be required to undergo, and to pay for, a non-routine on-site inspection.

1.12.c.2. A reviewing commissioner may waive the requirement for a non-routine inspection after a change of director if no substantive changes in the operation of the laboratory have been made and all the requirements of the governing Standards for Accreditation continue to be met.

1.12.c.3. Accreditation continues pending the outcome of the non-routine inspection or if the requirement for a non-routine inspection is waived.
1.13 Change of Ownership or Location

1.13.a. Accreditation by the CAP does not automatically continue upon change of ownership or location.

1.13.b. A laboratory must notify the CAP accreditation programs no later than 30 days prior to any change in ownership or location and provide appropriate demographic information.

1.13.c.1. Upon a change of ownership or location, the laboratory may be required to undergo, and pay for, a non-routine on-site inspection.

1.13.c.2. A reviewing commissioner may waive the requirement for a non-routine inspection, after change of ownership or location, if no substantive changes in the operation of the laboratory have been made and all the requirements of the governing Standard for Accreditation continue to be met.

1.13.c.3. If after change of ownership or location, the requirement for non-routine inspection is waived, the laboratory will retain its accreditation status.

1.14 Revision of Standards

1.14.a. The Commission on Laboratory Accreditation is responsible for assessing compliance with the Standards for Laboratory Accreditation, the Standards for Reproductive Laboratory Accreditation, the Standards for Forensic Drug Testing Laboratory Accreditation, and the Standards for Biorepository Accreditation (collectively “the Standards for Accreditation”).

1.14.b. Any proposed change in the Standards for Accreditation must be submitted to the commission for review.

1.14.c. Changes to the Standards for Accreditation recommended by the commission must be submitted to the Council on Accreditation for review and approval.

1.14.d. Changes to the Standards for Accreditation approved by the council must be submitted to the Board of Governors for review and approval for implementation.

1.16 Misrepresentation of Accreditation

1.16. Misrepresentation of accreditation or accreditation status by a laboratory may result in sanctions that may take the form of legal action, refusal to process applications or reapplications, or revocation of accreditation or other appropriate actions.

1.17 Investigation of Complaints

1.17.a. Definition: A complaint is the formal notification to the CAP or the discovery by the CAP of information outside of the routine inspection process that raises the possibility of non-compliance with the governing Standards for Accreditation and/or the accreditation checklist requirements in a CAP-accredited laboratory or in a laboratory seeking CAP accreditation.
1.17.b.1. The Commission on Laboratory Accreditation will investigate all complaints that meet the requirements of Section 1.17.a.

1.17.b.2. A complaint that involves an individual alleged misdiagnosis or misinterpretation, which, in the judgment of the Complaints Committee, is unrelated to the governing Standards for Accreditation or the accreditation checklists of the commission, does not meet the requirements of Section 1.17.a.

1.17.c.1 As part of the investigation of a complaint, the commission may require the laboratory to undergo and to pay for an inspection to determine whether the laboratory is in compliance with the governing Standards for Accreditation.

1.17.c.2. All reasonable efforts shall be made to maintain the confidentiality of investigational files.

1.17.c.3. All reasonable efforts shall be made to protect the complainant’s identity when the complaint was lodged in confidence.

1.17.d.1. At the conclusion of the complaint investigation, the responsible Complaints Committee member and regional commissioner will determine the outcome of each allegation within the complaint. The possible outcome categories are: substantiated; substantiated (not reportable); not substantiated; not applicable; and inconclusive.

1.17.d.2. If the Complaints Committee member and the regional commissioner are in disagreement over the outcome of an allegation, the matter will be referred to the entire committee for review and decision. The outcome shall be decided by a simple majority vote of the committee members.

1.17.d.3. The CAP accreditation programs will inform a complainant after a complaint investigation has been completed.

1.17.e. When the results of a complaint investigation indicate that a change in accreditation status may be merited, the laboratory shall be referred to the Accreditation Committee for review.

1.17.f.1. If a laboratory disagrees with the initial outcome determination, the laboratory may request an appeal by submitting a written request for reconsideration, along with appropriate documentation supporting the appeal, to the Complaints Committee within thirty days following receipt of the complaint notification letter.

1.17.f.2. The appeal will be referred to the full Complaints Committee for review. The Complaints Committee shall make a decision on the appeal within thirty days of such referral. The outcome shall be decided by a simple majority vote of committee members.

1.17.f.3. The laboratory will be notified in writing promptly after the decision is made.

1.17.f.4. If the original complaint outcome is overturned on appeal, the laboratory’s record will reflect the appeal review decision, the Accreditation Committee will be notified (if appropriate), and the appropriate oversight agencies will be notified.

1.18 Withdrawal From the CAP Accreditation Programs
1.18.a. A laboratory may withdraw from the CAP accreditation programs at any time.

1.18.b. To withdraw, a laboratory must submit a written request for withdrawal.

1.18.c. Accreditation will cease on the either the date of notification or a future date specified by the laboratory. The date specified may not be later than the laboratory’s anniversary date.

1.18.d. If the withdrawing laboratory is using CAP accreditation in lieu of Centers for Medicare and Medicaid licensure, any state licensure, or private organization accreditation requirements, the CAP will notify the respective agency or accrediting organization. Notification shall consist of the fact of withdrawal and, if deemed appropriate by CAP, any deficiencies cited if an inspection has occurred.

1.19 Conflict of Accreditation Requirements With Prevailing Law or Regulation

1.19. A laboratory shall not be required to comply with an individual accreditation checklist requirement if compliance would cause a laboratory to violate a state law or regulation. If a laboratory is cited for a deficiency and it can demonstrate to the satisfaction of the CAP’s Commission on Laboratory Accreditation that compliance would cause the laboratory to violate a state law or regulation, it shall not be required to remedy the deficiency. The deficiency will be expunged as not applicable.

1.20 Eligibility of Laboratories

1.20.a. Except as indicated in 1.20.b., the CAP will not inspect or accredit a laboratory that is not performing testing of specimens from human beings or animals.

1.20.b. When applicable law requires a laboratory to be (1) licensed in order to commence performing testing and/or (2) accredited before a license is issued, the CAP will inspect the laboratory’s facilities, policies and procedures. If the laboratory is in compliance with applicable requirements, it will be granted preliminary accreditation. The laboratory must undergo a complete inspection, within three months after testing commences. The laboratory will be charged additional fees for the subsequent inspection.

1.20.c. Notwithstanding anything to the contrary in this section or elsewhere in the policies, a laboratory may be deemed ineligible for participation in the CAP accreditation programs of the CAP if any of the following conditions exists:
   1. Its test menu includes a substantial number of tests that yield results whose methodology or clinical application is outside the expertise of the Commission on Laboratory Accreditation;
   2. Its test menu includes tests that depend on proprietary or otherwise confidential algorithm(s) not made available to the commission;
   3. Its test menu includes tests that depend on disclosed algorithms that have not been approved by the Food and Drug Administration, validated in published, peer-reviewed literature, or validated through methods acceptable to and understood by the commission;
   4. Its test menu includes tests that cannot be adequately evaluated because the commission’s accreditation checklists do not contain provisions necessary to cover the testing performed;
   5. The commission does not have adequate staff or inspector resources to perform...
the tasks required to conduct a complete and accurate inspection and reach a timely accreditation decision, or
6. The laboratory is, or at any time becomes, the subject of (a) an investigation by a government entity (including federal, state, local, or foreign entities) or (b) adverse media attention deemed by the commission to raise serious issues regarding the health or safety of patients or laboratory staff.

1.20.d. For purposes of subparagraph c.1, the term "substantial number of tests" means 20% or more of the laboratory’s test menu or 20% or more of the laboratory’s total test volume.

1.20.e. Denial of eligibility is not intended to express any opinion on the quality of the laboratory or the tests that it performs. Any laboratory deemed ineligible for participation in the CAP accreditation programs may seek accreditation by the Centers for Medicare and Medicaid Services, a state, or another private accreditation organization.

1.21 Probation with Probation


1.21.a.1. The Accreditation Committee may place a laboratory on probation in accordance with policy 1.21.b.

1.21.a.2. A decision to place a laboratory on probation will be promptly reported to the appropriate oversight agencies.

1.21.a.3. As a condition of accrediting a laboratory that has been placed on probation, the Accreditation Committee may require the laboratory to undergo, and to pay for, a non-routine inspection which may be announced or unannounced to determine whether the issues that led to the probation have satisfactorily been resolved. The Accreditation Committee may also require the laboratory to submit whatever additional documentation the Accreditation Committee deems necessary to determine whether such issues have been resolved.

1.21.a.4. If probation is removed, the Accreditation Committee will promptly notify the appropriate oversight agencies.


1.21.b.1. The Accreditation Committee may place a laboratory on probation if the findings are not deemed to pose a substantial risk of harm to patients and/or to laboratory personnel and any of the following conditions is present:
   1. Documentation available for review is insufficient to determine compliance with the governing Standards of Accreditation.
   2. The Accreditation Committee wishes to monitor the laboratory’s progress in correcting a deficiency or deficiencies.
   3. The laboratory has engaged in conduct contrary to the policies of the CAP accreditation programs but such conduct is not sufficient to warrant denial or revocation of accreditation.

1.21.b.2. A laboratory that is placed on probation may continue to provide testing or services as an accredited laboratory.
1.21.b.3. A laboratory that is on probation will remain on probation until the Accreditation Committee revokes or denies accreditation – or removes probation and accredits the laboratory.

1.21.c. Accreditation with Probation and Suspension.

1.21.c.1 The Accreditation Committee may place a laboratory on probation and suspend the accreditation of the laboratory or section(s) of that laboratory if documentation does not support compliance with the governing Standards of Accreditation of that laboratory or section(s).

1.21.c.2. A laboratory section or sections whose accreditation is suspended may not provide testing or services as an accredited laboratory.

1.21.c.3. A laboratory section or sections whose accreditation has been suspended will not be fully accredited until the Accreditation Committee determines that the issues that caused the suspension have been satisfactorily corrected.

1.21.c.4. If a laboratory section fails to demonstrate within 45 days that it is satisfactorily addressing the issues that caused the suspension, the accreditation status of the laboratory will be reconsidered by the Accreditation Committee.


1.21.d.1. The Accreditation Committee may assign probation with immediate jeopardy status to a laboratory when circumstances are identified that necessitate immediate corrective action. This situation may arise because a laboratory’s noncompliance with one or more critical requirements has caused, is causing, or is likely to cause serious injury, harm, or death to individuals served by the laboratory, laboratory workers, or visitors; and/or poses a serious risk to the health and safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public safety.

1.21.d.2. Assignment of such a status must be reported within 10 days to the Centers for Medicaid and Medicare Services and other applicable regulatory partners.

1.21.e. Reconsideration of Probation.

1.21.e.1. If a laboratory is placed on probation, it may formally request, in writing, reconsideration of the Accreditation Committee’s decision. The Accreditation Committee may reconsider its decision, provided the laboratory submits substantially new information/documentation that was available at the time of the inspection, and was not considered during the inspection and/or review process. This new information/documentation must constitute the basis for the request and reconsideration. At the discretion of the Accreditation Committee, this information is to be presented in writing, and/or in conjunction with a telephone conference.

1.22 Protection of Complainants or Whistle-Blowers

1.22. The Accreditation Committee may revoke the accreditation of, deny accreditation to, or take such other action as it deems appropriate with respect to any laboratory that has been found, directly or indirectly, to threaten, intimidate or retaliate against any individual for disclosing, or considering the disclosure of, information that might bear on the accreditation...
status of that laboratory.

1.23 Misrepresentation by a Participating Laboratory

1.23.a. The Accreditation Committee may revoke the accreditation of, deny accreditation to, or impose other sanctions against any laboratory that makes a misrepresentation relating to the CAP accreditation programs.

1.23.b. A misrepresentation for purposes of this section includes, but is not limited to a false statement of fact about the laboratory or its operations; fabrication or alteration of information, records or other documentation; failure to advise the CAP accreditation programs of facts or developments that may bear on the CAP’s evaluation of the laboratory; and misstatement of the accreditation status of the laboratory. A misrepresentation may be in writing, oral, or through failure to provide material information.

1.24 Investigations and Media Attention

1.24.a. A laboratory must notify the CAP as soon as it finds itself to be the subject of an investigation by a state or federal agency or by another accreditation organization. The laboratory must provide copies of the agency’s correspondence and/or reports, as appropriate.

1.24.b. A laboratory must notify the CAP as soon as it finds itself to be the subject of adverse media attention. A written summary of the allegation(s) must be provided to the CAP.

1.24.c. A laboratory must notify the CAP if it discovers actions by laboratory personnel that violate federal, state or local laws that regulate laboratories or biorepositories. A written summary of the incident(s) must be provided to the CAP.

1.24.d. The laboratory must provide written documentation of any actions that have been taken or are planned.

1.24.e. The CAP will investigate an incidence of an investigation by a state or federal agency or by another accreditation organization or adverse media attention like a complaint (see policy 1.17 Investigation of Complaints).

1.25 Preliminary Accreditation

1.25.a. Preliminary accreditation is granted in cases where:
   1. There is an urgent need for an accreditation decision prior to the usual course of action for full accreditation of a laboratory currently performing testing, or;
   2. Accreditation is required prior to the commencement of patient/subject testing, e.g., Florida initial laboratories and clinical drug trial laboratories.

1.25.a.1. The status of preliminary accreditation may remain in effect for up to one year after which time the accreditation will lapse.
   1. The expectation is that significant progress in achieving accreditation is occurring during this time.
   2. A central office/reviewing commissioner assessment of the laboratory will occur
six months after the onsite inspection if testing has not commenced.

1.25.a.2. The reviewing commissioner may recommend preliminary accreditation prior to accreditation if the findings as reviewed by the CAP accreditation program technical specialist are deemed to not pose a substantial risk of harm to patients and/or to laboratory personnel and any of the following conditions is present:
   1. The Part A general questions have been answered in the affirmative.
   2. Deficiencies appear to be resolvable within a 30-day time period.

1.25.a.3 Preliminary accreditation may be applicable for laboratories that have completed their initial on-site inspection, but patient/subject testing has not commenced. Preliminary accreditation may be recommended by the reviewing commissioner at the end of the routine process, e.g., not before responses to deficiencies have been reviewed. A final decision will be deferred until re-inspection has occurred after initiation of testing as defined above.

1.26. Proficiency Testing Programs

1.26.a. The Commission on Laboratory Accreditation through the Continuous Compliance Committee shall determine the acceptance of proficiency testing providers. The commission may remove the acceptance of any proficiency testing provider if, in the sole judgment of the commission, the provider has failed to comply with the commission’s requirements.

1.26.b. The CAP accepts proficiency testing programs on an analyte by analyte or activity by activity basis.

1.26.c. For analytes that are regulated by the Centers for Medicare and Medicaid Services (CMS), laboratories subject to CLIA must use CAP-accepted proficiency testing programs that are approved by the CMS.

1.26.d. CAP acceptance of a program shall be conditioned on the program initially and continuously complying with a set of criteria that address program scoring, statistical methodologies, evaluation, proficiency testing result reporting, staff qualifications, quality control of proficiency testing materials, data communication between the proficiency testing program and the CAP, and the application of applicable quality management systems.

1.26.e. The CAP accreditation programs will monitor ongoing compliance with the acceptance criteria and rate of ungraded challenges for each accepted proficiency testing program.

1.26.f. Criteria for acceptance of proficiency testing providers may be updated and modified by the commission. Proficiency testing providers will be given a reasonable period of time to bring their programs in conformance with updated standards.

1.27 Denial of Eligibility after Application for Accreditation

1.27.a.1. The Commission on Laboratory Accreditation may deny a laboratory that has submitted an application for accreditation based on eligibility when it fails to meet the governing CAP Standards for Accreditation or when the laboratory fails to comply with the policies and procedures of the CAP accreditation programs. Denial of eligibility applies to laboratories seeking initial accreditation and accredited laboratories that are reapplying.
1.27.b.1 A laboratory whose eligibility for accreditation is denied shall be notified by express delivery, signature required.

1.27.c.1. If a laboratory is using CAP Accreditation in lieu of Centers for Medicare and Medicaid Services (CMS) licensure, CMS will be notified of the denial of accreditation application eligibility.

1.27.c.2. If a laboratory is using CAP Accreditation in lieu of state licensure in an exempt state, the state will be notified of the denial of accreditation application eligibility.

1.27.d.1. A laboratory whose eligibility for accreditation has been denied by the commission may seek reconsideration by the commission based on information that it presents to the commission within 30 days after notification of the denial decision based on the date of the notification letter (i.e., not the date the letter is received by the laboratory). A laboratory appealing a decision must submit documents supporting its position, preferably electronically. Furthermore, the director of the appealing laboratory may be asked to participate in a conference call to explain its request.

1.27.d.2. In the event that the commission reaffirms its decision, a laboratory whose accreditation application eligibility has been denied by the commission may appeal the decision to the Council on Accreditation within 30 days after notification of the reaffirmation based on the date of the notification letter (i.e., not the date the letter is received by the laboratory).

1.27.d.3. The council shall consider a properly filed appeal within 30 days following receipt of the appeal.

1.27.d.4. The council shall review each appeal and make a determination whether to invite representatives of the laboratory, at their expense, to appear before the council, in person or via conference call, to present and clarify relevant facts and to answer questions posed by the council members. This determination shall be conveyed to the laboratory within 10 days following review of the appeal.

1.27.d.5. The council shall act on any appeal at the meeting at which the appeal is heard unless the council determines that it requires additional information. If the council requests additional information, it shall decide the appeal at its next regularly scheduled meeting.

1.27.d.6. The decision of the council on an appeal shall be conveyed to the laboratory promptly after the decision is made.

1.27.d.7. Neither request for reconsideration by the commission nor appeal to the council shall stay the denial of accreditation application eligibility.

1.27.d.8. If the denial of accreditation application eligibility is overturned on reconsideration or appeal, the laboratory’s application will be reinstated as of the time of the reversal, and the appropriate oversight agencies will be notified of the decision.

1.27.e.1. A laboratory whose eligibility for accreditation has been denied may only re-apply after it has first fully addressed all of the issues that resulted in the denial action.

1.27.f.1. A laboratory whose accreditation application eligibility has been denied and that has chosen to reapply for accreditation will be assessed fees equal to those fees assessed
for a new application.

1.28. Deferral of Initial Accreditation Decision

1.28.a. The Accreditation Committee may defer making an initial accreditation decision on a laboratory if the committee finds any of the following conditions is present:

1. There is insufficient documentation to determine if the laboratory is, or will remain, in compliance with the governing Standards of Accreditation.
2. The Accreditation Committee wishes to monitor the laboratory’s progress in the correction of deficiencies.
3. The laboratory has engaged in conduct contrary to the policies of the CAP accreditation programs but such conduct is not sufficient to warrant denial of accreditation.

1.28.b. The Accreditation Committee may require a laboratory for which it has deferred an initial accreditation decision to undergo, and to pay for, a non-routine inspection, announced or unannounced, to determine whether the issues that led the Accreditation Committee to defer its initial accreditation decision have been resolved satisfactorily. The Accreditation Committee may also require the laboratory to submit whatever documentation the Accreditation Committee deems necessary to determine whether such issues have been resolved.

2. INSPECTION

2.01 Conflicts of Interest

2.01.a. 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 accreditation programs. To that end, the following prohibitions apply:

2.01.a.1. No inspector may be engaged in a close personal, family, business or professional relationship with any personnel in a laboratory that the inspector inspects.

2.01.a.2. No inspector may solicit or accept, and no inspected laboratory or its parent institution or associated entity may offer or provide, cash or non-cash gifts, except those of modest value, including personal gifts, products, services or entertainment provided at no cost or unreasonably discounted cost.

2.01.a.3. No inspector may either formally or informally discuss, solicit or accept, and no inspected laboratory or its parent institution or associated entity may either formally or informally discuss, offer to provide or provide, an employment or consulting arrangement, referral of business, or other business opportunity.

2.01.b.1. Prior to finalization of an inspector assignment, every inspector must disclose to the CAP accreditation programs any facts or relationships that are inconsistent with the above prohibitions, and any other potential conflicts of interest.

2.01.b.2. The above prohibitions shall apply through the course of the inspection and for 75 days after the date of the inspection.

2.01.c.1. An inspector who is found to have violated one of the above prohibitions shall be referred to the Inspection Process Committee of the Commission on Laboratory Accreditation
and may be subject to sanctions, including loss of eligibility to serve as a CAP accreditation program inspector.

2.01.c.2. A laboratory, or its parent institution or associated entity, that is found to have violated one of the above prohibitions shall be referred to the Complaints and Investigations Committee of the commission for investigation and may be subject to sanctions including: requiring the laboratory to undergo and to pay for an additional inspection (which may be announced or unannounced); refusal to process accreditation reapplications; probation or suspension of accreditation; or denial or revocation of accreditation. Any decision of the Complaints and Investigations Committee that may impact the accreditation decision will be referred to the Accreditation Committee.

2.02 Size and Composition of Inspection Team

2.02.a. The inspection team leader, in conjunction with CAP accreditation programs staff, shall determine the size and composition of the inspection team. Inspection team leaders who consistently take an inappropriately sized team, or an inappropriate team composition, will first be counseled by the appropriate regional or state commissioner. If the inspection team leader continues to take an inappropriately sized team, or an inappropriately composed team following counseling, the inspection team leader will be referred to the Inspection Process Committee as a “Do Not Use” inspector.

2.02.b. Inspection team leaders are responsible to ensure that appropriately credentialed specialty inspectors are used when inspecting cytogenetics, molecular pathology, histocompatibility and flow cytometry laboratories, or laboratories utilizing these checklists.

2.02.c. Each inspector is obligated to act in an unbiased and objective manner when conducting an inspection. If an inspection team member works for or otherwise has a direct reporting relationship to the team leader or another team member, both individuals should be cautious to retain objectivity in fact finding throughout the inspection process.

2.02.d. Generally, for international inspections, the team leader will be US-based and will be required to include appropriately qualified certified international inspectors as team members whenever possible or practical.

2.03 Non-routine Inspections

2.03.a. The Commission on Laboratory Accreditation, the committees of the commission, or the Accreditation Committee may require a non-routine inspection, if there is evidence to indicate that the laboratory may be out of compliance with the governing Standards for Accreditation. Such an inspection may focus on the area(s) suspected to be out of compliance with the standards, but could also involve the entire laboratory and all its subspecialty areas. The inspection may be announced or unannounced.

2.04 Laboratory Self-Inspections

2.04.a. Laboratories enrolled in the CAP accreditation programs must perform a self-inspection in interim years.
2.04.b. Laboratories shall prepare a list of deficiencies identified during the course of the self-inspection and document corrective action when deficiencies are noted.

2.04.c. The list of deficiencies, if any, identified during the course of the self-inspection and documentation of corrective action(s) shall be made available to the inspection team leader at the next on-site inspection along with the completed Self-Inspection Instructions and Verification Form.

2.04.d. Laboratories must notify the CAP when they have completed their interim self-inspection.

2.04.e. Failure to notify the CAP accreditation programs that the interim self-inspection has been completed may result in revocation of accreditation.

2.05 Confidentiality of Inspection Findings

2.05. Inspection findings, including health information about any identifiable individual, are intended to be confidential. Inspectors should limit discussion of inspection findings to individuals or entities associated with the inspection process, unless appropriate documented consent has been obtained for their release to others.

2.06 Appeal of Inspector Assignments

2.06. If the laboratory to be inspected has justifiable reason/just cause to believe that the named inspector cannot perform the inspection without bias, the laboratory may request appointment of a different inspector within 30 days of notification of assignment. A laboratory may appeal an inspector assignment in writing first to the assigning commissioner, then to the appropriate regional commissioner and finally to the chair of the Commission on Laboratory Accreditation if it believes that it cannot receive an objective inspection.

Explanatory note: Competition between a laboratory (or its parent institution) providing an inspection team and the laboratory (or its parent institution) to be inspected does not itself represent conflict of interest. The CAP believes that, in such circumstance, team leaders and inspectors will conduct the inspection professionally and in an objective manner.

The CAP believes that the review of the inspection findings and the laboratory's responses to the cited deficiencies by the reviewing commissioner ensures an appropriately objective accreditation decision.

2.07 Use of Checklists

2.07.a. At least one discipline-specific checklist for each discipline in which a laboratory offers patient testing and one All Common Checklist for each section unit must be used to conduct a routine or self-inspection.

2.07.b. All non-routine inspections must include a Laboratory General Checklist, any discipline-specific checklists deemed necessary, and an All Common Checklist per section unit.

2.07.c. All routine and non-routine inspections for biorepository laboratories must include a Laboratory General Checklist and the Biorepository Accreditation Program Checklist.
2.08 Source of Inspection Team

2.08.a. The inspection team leader for a laboratory must not be in a business, professional
or personal relationship that would preclude an objective inspection of that laboratory.

2.08.b. A laboratory should not serve as the source of the inspection team leader (or team
members) for the inspection of the laboratory that provided the inspection team leader (and
team members) for its immediate past inspection.

2.08.c. A laboratory should not serve as the source of the inspection team leader (or
team members) for the inspection of the same laboratory for two consecutive on-site
inspections.

2.09 Intentionally left blank

2.10 Routine Inspections

2.10.a. Except as noted, routine inspections will be conducted within the three-month
period prior to the laboratory’s anniversary date. Laboratories will not be informed of the
inspection date.

2.10.b. Laboratories subject to unannounced inspections will be informed of the identity of
the inspection team leader prior to the inspection, but will not be notified of the inspection
date.

2.10.c.1. Initial accreditation inspection dates will be announced.

2.10.c.2. International laboratory inspections, excluding Canadian laboratory inspections,
should occur within the 90 days prior to the anniversary date and will be announced.

2.10.c.3. Reproductive Laboratory Accreditation Program inspections should occur within the
90 days prior to the anniversary date and will be announced.

2.10.c.4. Forensic Drug Testing Accreditation Program inspections should occur within the
90 days prior to the anniversary date and will be announced.

2.11 Do Not Use Status of Institutions and Inspectors

2.11.a. Institutions are automatically marked “Do Not Use” when a sanction of Probation
or Suspension is applied, and is applicable for the duration of the sanction plus the 90
days following the expiration of the sanction.

2.11.a.1. An institution may be marked “Do Not Use” at the discretion of the Accreditation
Committee, Inspection Process Committee, Complaints Committee, Commission on
Laboratory Accreditation, or Council on Accreditation.

2.11.b. An individual who has performed outside of established policy will be marked “Do Not
Use” and referred to the Inspection Process Committee for review and final determination.
2.11.b.1. The Inspection Process Committee will determine the appropriate resolution for inspectors who have been referred due to performance issues. Such resolutions may include, but are not limited to, requiring retraining, mentoring with an experienced inspector, placing temporarily on “Do Not Use” status, or placing permanently on “Do Not Use” status.
3. INSPECTORS

3.01 Reimbursement of Travel Expenses

3.01.a. Travel arrangements must be made through the CAP Travel Desk if any air travel is required.

3.01.b. Hotel reservations must be made through the CAP Travel Desk if more than 10 hotel nights are involved.

3.01.c. An inspection team may use a charter flight when inspecting laboratories not readily accessible by scheduled commercial carriers and when the cost of the flight compares favorably with costs that would have been incurred using scheduled commercial carriers. In such instances, the flight must be approved in advance and a special “charter flight” expense sheet must be completed.

3.01.d. The chair of the Commission on Laboratory Accreditation must review and approve (or deny) unusual requests for reimbursement.

3.02 Inspector Team Leaders, Inspectors, and Inspection Team Composition

3.02.a. Inspection team leaders may be appointed by assigning or reviewing commissioners, the chair and vice chair of the Commission on Laboratory Accreditation, and by CAP accreditation programs staff with oversight by the commission.

3.02.b.1. Pathologist Inspection Team Leader. Whenever appropriate the inspection team leader shall be a board-certified pathologist and preferably affiliated with a CAP-accredited laboratory.

3.02.b.2. Non-Pathologist Inspection Team Leader. A non-pathologist laboratory director may be an inspection team leader. However, in those instances in which the laboratory offers services in either anatomic or cytologic pathology, the inspector for anatomic pathology must be a pathologist.

3.02.b.3. Staff Inspector Inspection Team Leader. A medical technologist with expertise in the area to be inspected may be an inspection team leader.

3.02.c.1. Inspection Team Members. Inspection team members may include pathologists, residents in pathology, clinical scientists, medical technologists, computer specialists and others, as appropriate.

3.02.c.2. Specialty inspectors who have had their credentials verified and approved by the appropriate resource committee should be included as a team member on inspection teams that include the following checklists: cytogenetics, molecular pathology, clinical biochemical genetics, histocompatibility, and flow cytometry.

3.02.c.3. A qualified technologist with substantial experience in the areas under review can inspect anatomic pathology sections of a laboratory under the supervision of a pathologist. The inspector for cytopathology must be a pathologist or a cytotechnologist who is actively engaged in the practice of cytopathology.
3.02.d. Assignment of Inspection Team Leaders. When necessary to avoid conflicts of interest, the chair will act as assigning and reviewing commissioner for the laboratories associated with reviewing commissioners and the vice chair. The vice chair will act as assigning and reviewing commissioner for the chair's laboratory.

3.02.e. Certified International Inspectors. Team leaders will be required to include appropriately qualified certified international inspectors as team members for all international inspections whenever possible and practical.

3.03 Inspector Training Requirements

3.03.a.1. Inspection team leaders must successfully complete training as specified by the Commission on Laboratory Accreditation within the two years prior to leading an inspection team.

3.03.a.2. All team leaders, including individuals who may have participated in an inspection as a team member, must successfully complete team leader initial training and demonstrate proficiency in the following content:
   1. Core program information (including all relevant CAP Standards for Accreditation and CLIA requirements)
   2. Team leader responsibilities
   3. Inspection techniques
   4. Other elements as designated by the commission

3.03.a.3. Trained team leaders must continue to demonstrate proficiency by repeating team leader initial training or completing team leader update training.

3.03.b.1. Inspection team members must successfully complete training as specified by the commission within the two years prior to conducting an inspection.

3.03.b.2. All team members must successfully complete team member initial training and demonstrate proficiency in the following content:
   1. Core program information (including all relevant CAP Standards for Accreditation and CLIA requirements)
   2. Team member responsibilities
   3. Inspection techniques
   4. Other elements as designated by the commission

3.03.b.3. Trained team members must demonstrate proficiency by repeating team member initial training or completing team member update training.

3.03.c.1. Inspectors based outside of the US must successfully complete the International Inspection Certification Program (IICP) and demonstrate proficiency in the following content:
   1. Core program information (including all relevant CAP standards)
   2. Team member responsibilities
   3. Inspection techniques
   4. Other elements as designated by the commission

3.03.c.2. Certified international inspectors must continue to demonstrate proficiency by performing at least one inspection per year (if asked) and completing team member update
training every two years.

3.03.c.3. Inspectors based outside of the US may be included in the IICP if they meet all the following criteria:
   1. Currently affiliated with a CAP-accredited laboratory, a laboratory that has applied for CAP accreditation, or a laboratory that will seek CAP accreditation within two years
   2. Performed a minimum of two inspections within the past three years
   3. Successfully completed the online team member initial training course or team member training update course within the past two years; or, if inspector training status is not current, successfully completes the IICP examination
The CAP certification mark recognizes your organization for achieving CAP accreditation, something you share with more than 7,000 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.

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