## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td>Commission Philosophies</td>
<td>10</td>
</tr>
<tr>
<td>Applying to CAP Accreditation Program</td>
<td>14</td>
</tr>
<tr>
<td>Preparation of Application Materials</td>
<td>16</td>
</tr>
<tr>
<td>Preparing for the Inspection</td>
<td>21</td>
</tr>
<tr>
<td>Conducting the Inspection: General Principles and Meetings</td>
<td>29</td>
</tr>
<tr>
<td>Inspecting the Laboratory Sections</td>
<td>40</td>
</tr>
<tr>
<td>Requirements Applicable to all Laboratory Sections</td>
<td>40</td>
</tr>
<tr>
<td>Laboratory General</td>
<td>42</td>
</tr>
<tr>
<td>Conducting the Safety Inspection</td>
<td>48</td>
</tr>
<tr>
<td>All Common</td>
<td>53</td>
</tr>
<tr>
<td>Anatomic Pathology</td>
<td>63</td>
</tr>
<tr>
<td>Chemistry and Toxicology</td>
<td>69</td>
</tr>
<tr>
<td>Clinical Biochemical Genetics</td>
<td>72</td>
</tr>
<tr>
<td>Cytogenetics</td>
<td>75</td>
</tr>
<tr>
<td>Cytopathology</td>
<td>78</td>
</tr>
<tr>
<td>Flow Cytometry</td>
<td>84</td>
</tr>
<tr>
<td>Hematology and Coagulation</td>
<td>86</td>
</tr>
<tr>
<td>Histocompatibility</td>
<td>90</td>
</tr>
<tr>
<td>Immunology</td>
<td>93</td>
</tr>
<tr>
<td>Microbiology</td>
<td>94</td>
</tr>
<tr>
<td>Molecular Pathology</td>
<td>99</td>
</tr>
<tr>
<td>Point-of-Care Testing</td>
<td>102</td>
</tr>
<tr>
<td>Team Leader Assessment of Director &amp; Quality Checklist</td>
<td>106</td>
</tr>
<tr>
<td>Transfusion Medicine</td>
<td>109</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>111</td>
</tr>
<tr>
<td>Reproductive Laboratories (RLAP)</td>
<td>112</td>
</tr>
<tr>
<td>Forensic Drug Testing Laboratories (FDT)</td>
<td>115</td>
</tr>
<tr>
<td>Biorepository Facilities (BAP)</td>
<td>117</td>
</tr>
<tr>
<td>Inspecting Other Types of Laboratories</td>
<td>120</td>
</tr>
<tr>
<td>The Inspection Report</td>
<td>125</td>
</tr>
<tr>
<td>The Summation Conference</td>
<td>126</td>
</tr>
<tr>
<td>Post-Inspection for the Inspection Team</td>
<td>131</td>
</tr>
<tr>
<td>Post-Inspection for the Laboratory</td>
<td>132</td>
</tr>
<tr>
<td>Maintaining Accreditation</td>
<td>139</td>
</tr>
<tr>
<td>Nonroutine Inspections</td>
<td>145</td>
</tr>
<tr>
<td>Appendices</td>
<td>148</td>
</tr>
<tr>
<td>Appendix A: CAP Checklist Usage</td>
<td>148</td>
</tr>
<tr>
<td>Appendix B: Guidelines for Determining Test Volume</td>
<td>154</td>
</tr>
</tbody>
</table>
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix C: Announced and Unannounced Inspections: Tips for Laboratories and Site Coordinators</td>
<td>156</td>
</tr>
<tr>
<td>Appendix D: Sample of Inspection Confirmation Letter to Laboratory Director</td>
<td>160</td>
</tr>
<tr>
<td>Appendix E: Laboratory General Activity Menu Reference Guide</td>
<td>163</td>
</tr>
<tr>
<td>Appendix F: Retention of Laboratory Records and Materials</td>
<td>165</td>
</tr>
<tr>
<td>Appendix G: Glossary of Terms</td>
<td>168</td>
</tr>
<tr>
<td>Appendix H: Accreditation Requirements When a PT Result Is Linked to an Exception Reason Code</td>
<td>189</td>
</tr>
<tr>
<td>Appendix I: CAP Accreditation Program Policies</td>
<td>192</td>
</tr>
</tbody>
</table>
INTRODUCTION

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of this Manual</td>
<td>3</td>
</tr>
<tr>
<td>Overview of Accreditation Program</td>
<td>3</td>
</tr>
<tr>
<td>Accreditation Hierarchy</td>
<td>4</td>
</tr>
<tr>
<td>Commissioners</td>
<td>5</td>
</tr>
<tr>
<td>Inspectors and CAP Staff</td>
<td>5</td>
</tr>
<tr>
<td>Accreditation Documents</td>
<td>5</td>
</tr>
<tr>
<td>Communication of Changes to CAP Accreditation Programs</td>
<td>6</td>
</tr>
<tr>
<td>Standards for CAP Accreditation Programs</td>
<td>6</td>
</tr>
<tr>
<td>Accreditation Checklists</td>
<td>6</td>
</tr>
<tr>
<td>Identifying Checklist Changes</td>
<td>7</td>
</tr>
<tr>
<td>Phase 0, Phase I, and Phase II Deficiencies</td>
<td>8</td>
</tr>
<tr>
<td>Checklist Components</td>
<td>8</td>
</tr>
</tbody>
</table>

Purpose of this Manual

The Laboratory Accreditation Manual is intended to provide laboratories and inspectors a basic overview on the CAP’s accreditation programs and accreditation processes. The detailed accreditation requirements used for inspection are found in the CAP’s accreditation checklists. CAP-accredited laboratories and biorepositories must be in compliance with the checklist version effective at the time of application or reapplication. Requirements published in the checklists supersede information published in this manual.

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, the Centers for Medicare and Medicaid Services (CMS), an agency within the US Department of Health and Human Services, approved the CAP as an accrediting organization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CAP laboratory accreditation offers the broadest scope of disciplines of any approved accreditation program. Other CAP accreditation programs and year of introduction include: 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 the CAP 15189 program, a voluntary nonregulated accreditation program related to the International Organization for Standardization (ISO) 15189:2007 Standard. CAP 15189 has its own standards and policies not addressed in the Laboratory Accreditation Manual. It does not replace the CLIA-based Laboratory Accreditation Program.
(LAP), but rather complements LAP 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 (LAP, BAP, FDT, and RLAP) were all created with the primary objective of improving the quality of clinical laboratory services. They 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 total, the CAP accredits more than 7,800 laboratories.

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

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

**Accreditation Hierarchy**

The Council on Accreditation (CoA) sets the strategic direction for the CAP’s laboratory accreditation programs, in accordance with the CAP’s vision, and monitors its overall effectiveness in ensuring that participating laboratories meet regulatory and CAP requirements. The CoA also provides oversight to the Commission on Laboratory Accreditation (CLA), a group of qualified pathologists appointed to advance the CAP’s accreditation programs as the prime exemplar for the inspection and accreditation of medical laboratories and biorepositories; to administer the programs through the principles of peer review and education; to further 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 laboratory director’s role in clinical decision making and consultation.

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) the inspection processes, (iii) inter-inspection 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’s Accreditation programs. The CLA uses the expertise of numerous CAP scientific resource committees to keep the programs and their requirements abreast of new developments in laboratory medicine.
The Accreditation Committee is another arm of the CoA, and is responsible for ensuring objectivity and consistency in CAP accreditation decisions by centralizing the decision-making process and criteria. The Accreditation Committee is responsible for all accreditation status decisions, including suspension and probation, based on the recommendations from the reviewing commissioners, technical specialists, and other LAP committees as appropriate.

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. They are responsible for providing feedback and mentoring to volunteer inspectors.

Inspectors and CAP Staff

The inspectors who conduct the on-site laboratory inspections are the lifeblood of the 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 that meet defined criteria.

Accreditation Documents

In addition to this manual, three other documents are fundamental to the inspection process: 1) the Standards for Laboratory Accreditation (the Standards), 2) the Accreditation Checklists, and 3) the Inspector’s Summation Report (ISR). Through peer review, the inspector uses the checklists to determine if the laboratory meets the criteria set out in the Standards. The inspector collects information and records it on the ISR, 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 of information and ideas between the members of the inspection team and the 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 new ideas or processes back to their own laboratories.
Communication of Changes to 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 CAP’s accreditation programs. The objective of the Standards is to ensure that accredited laboratories meet the needs of patients, physicians, and other health care practitioners. The CAP accredits laboratories that conform to the Standards. Each of the four accreditation programs has its own Standards for Accreditation. The CAP Board of Governors approves these standards, which have evolved through years of study and continuous review by the CLA and CoA. The inspector must be familiar with each standard and its interpretation. A copy of the Standards is included with each inspection packet, and must be reviewed before the inspection of the laboratory. The inspection team leader is considered the on-site authority for the interpretation of these standards.

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

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

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

Standard IV includes the administrative requirements of the program. Laboratories must comply with the requirements specified in the Standards, the terms of accreditation, and the accreditation checklists. On-site inspection by an external team and an interim self-inspection are the cornerstones of the inspection requirement. Participating laboratories also provide an inspection team when requested.

Accreditation Checklists

Each checklist is a detailed list of requirements that the inspector uses to determine if the laboratory meets the Standards. Each requirement is uniquely numbered and indicated by a declarative statement. The checklists 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 prior to the on-site inspection and at accreditation mid-cycle 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 cap.org by opting in to the CAP e-LAB Solutions Suite page.

A laboratory will be inspected using the checklist version effective 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 for the checklist version sent for use in the self-inspection to be different from the versions used for the previous or next on-site inspection.

Identifying Checklist Changes

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

New checklist requirements are marked with a “NEW” flag and the date of the edition in which the requirement first appeared. 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.
Each checklist is available in the following three versions on cap.org by opting in to the CAP e-LAB Solutions Suite page:

- CAP current
- On-site 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

To hear the most recent “Checklists Update” webinar, visit the CAP’s website at cap.org; log in to the e-LAB Solutions Suite; under CAP Accreditation, choose CAP Accreditation Resources. The annual checklist update is under Educational Resources.

**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 supporting documentation 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 into the e-LAB Solutions Suite via cap.org.

The website checklist format not only includes checklist requirements, but it also includes the following additional components that may be helpful to the laboratory in determining compliance:

1. **Subject Header**: 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: examples that suggest ways to document compliance with the requirement. Some elements listed are required. This information is intended to assist the laboratory and drive consistent understanding of the requirement.

3. R·O·A·D (Read, Observe, Ask, Discover): an inspection tool that shows the inspector how to assess compliance through focusing on a group of related requirements rather than assessing each requirement individually.

4. NOTE: information that provides additional details to assist in interpreting the requirement. Information in the NOTE is considered integral to the requirement and must be complied with as part of the checklist requirement itself.

5. References: additional resources that may be helpful to the laboratory in determining compliance and corrective action.
COMMISSION PHILOSOPHIES

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer Review</td>
<td>10</td>
</tr>
<tr>
<td>Thoroughness</td>
<td>10</td>
</tr>
<tr>
<td>Judgment</td>
<td>11</td>
</tr>
<tr>
<td>Disputes</td>
<td>11</td>
</tr>
<tr>
<td>Harassment</td>
<td>11</td>
</tr>
<tr>
<td>Solicitation</td>
<td>11</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>12</td>
</tr>
<tr>
<td>Confidentiality – HIPAA Privacy Rule and HITECH Act</td>
<td>12</td>
</tr>
<tr>
<td>Inspector Liability</td>
<td>12</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>13</td>
</tr>
</tbody>
</table>

**Peer Review**

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

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

- As representatives of the accreditation program and the CAP, inspectors must strive to be objective and fair. There is often more than one way to comply with a requirement.
- The inspection team leader should be a peer of the laboratory director.
- Deficiencies should be presented factually. Provide recommendations for improvement if possible.
- A negative, unduly critical, or punitive attitude should be avoided.
- Deficiencies cited by the inspection team may be challenged. If resolution of a disagreement between laboratory personnel and an inspector cannot be achieved before or during the summation conference, the laboratory may challenge the deficiency during the post-inspection process. For more information, refer to the section Post-inspection for the Laboratory - Challenging a Deficiency in this manual.

**Thoroughness**

The CAP inspection process is approved by the Centers for Medicare and Medicaid Services (CMS) and must meet all federal regulatory requirements. Additionally, participating laboratories expect a thorough, detailed, and fair inspection. All pertinent items in the customized checklist must be inspected. Since laboratories must be inspection-ready at all times, as part of providing
quality patient care, they appreciate validation of the work they do and deserve a comprehensive inspection. A deficiency should not be overlooked because it seems minor.

**Judgment**

The Commission relies upon the inspector’s judgment more than any other attribute in the assessment of a laboratory. This attribute is, however, the most difficult to standardize. There will be occasions when a conscientious inspector will have difficulty deciding whether a laboratory is in compliance with a checklist requirement. Many of these decisions involve assessment of partial compliance with the checklist requirement. Therefore, the inspector must describe the observations as completely as possible in the Inspector’s Summation Report. This description should include details of the sampling that was performed to assess compliance with the requirement. For example, a description may include, “In the review of xx number of records for a specific expected result, the laboratory was found to be out-of-compliance with 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 and/or laboratory personnel may contact the CAP’s accreditation technical staff by telephone during the inspection (800-323-4040 ext 6065). Following the inspection, if a laboratory wishes to challenge a particular citation, it must state its disagreement in the deficiency response and provide documentation to demonstrate how it was in compliance before it was inspected. The regional commissioner will review disputed items and determine if the deficiency can be removed from the inspection record.

**Harassment**

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

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

Employees of laboratories should report inappropriate conduct on the part of CAP team leaders or team members to CAP headquarters. The CAP does not tolerate harassment. In cases of documented harassment, the CAP will take appropriate action.

**Solicitation**

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

Confidentiality

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

Confidentiality – HIPAA Privacy Rule and HITECH Act

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

The CAP further protects the CAP-accredited laboratory by requiring all CAP inspectors to attest on the inspection report that they will keep any patient information confidential and use it only for purposes of the CAP inspection. Other CAP personnel or agents who may have access to protected health information are trained concerning their obligation to keep this information confidential and to use such information only within the context of the inspection and accreditation services provided to the laboratory. In addition, the CAP requires that laboratories submit only documentation and other materials to the CAP that have been de-identified of all protected health information (PHI), as that term is defined in 45 C.F.R. Parts 160 and 164, in accordance with HIPAA and its implementing regulations (see 45 C.F.R. § 164.514(b)) unless the laboratory must submit PHI to the CAP in order to respond to a deficiency or complaint investigation.

Inspector Liability

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

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

The inspection team does not make the accreditation decision, and the subject laboratory may challenge any deficiency citation. Further, the CLA believes that team leaders and inspectors will conduct inspections objectively and professionally, regardless of whether they are in competition with the subject institution. Prior to unannounced inspections, the CAP requires team leaders to sign a statement attesting to the absence of conflict of interest.

The laboratory is notified in advance of the team leader’s name and institution. However, the laboratory should not contact the inspector, even if a conflict of interest should be apparent. Instead, prior to the inspection, the laboratory may discuss the specifics of a perceived conflict of interest with CAP staff or the state and/or regional commissioner, or complete and return the conflict of interest form that is found in the self-inspection materials. CAP headquarters will evaluate and discuss this information with the state or regional commissioners for final determination. All state or regional commissioners have discretion to recommend reassignment if there appears to be a valid conflict of interest. A laboratory may notify CAP headquarters of perceived conflicts when the inspection assignment is made. However, the CAP may determine at any time that the perceived conflict of interest is not valid and the laboratory may not be reassigned to a new inspection team. The laboratory should not contact the assigned inspector.
Proficiency Testing (PT) Prerequisite

• Each separately accredited laboratory must periodically assess the accuracy of each patient-reportable test that is performed under its own CAP number.

• For analytes that require external proficiency testing (PT), each laboratory must enroll and participate in a CAP-accepted PT program. (See glossary for the definition of CAP-accepted PT program.) PT enrollment requirements may be found in the Master Activity Menu with PT Options, which is available through e-LAB Solutions Suite or the Analyte/Procedure Index of the CAP Surveys catalog.

• For tests that do not require enrollment in a CAP-accepted PT program, the laboratory must perform an alternative performance assessment semiannually to determine the reliability of testing. The most common way to do this is by purchasing an external PT product if available. Other acceptable alternative performance assessment procedures are listed in the Accreditation Checklists and in the Inspecting the Laboratory Sections – All Common section of this manual.

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

Application

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 the application materials to the laboratory. The application materials are organized into a binder in four sections, including all the necessary forms for the formal application, as well as sections to store post-inspection and self-inspection materials, the Standards for Laboratory Accreditation, and this manual. The master version of the inspection checklists is available on cap.org by opting in through the CAP’s e-LAB Solutions Suite. A letter from the CAP confirming that the laboratory is in the application process is included in the binder and may be used to show 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 preferred method of completing the application is through the online portal at cap.org through the e-LAB Solutions Suite. Alternatively, paper applications can be mailed to the CAP headquarters. The application materials for the Biorepository Accreditation Program are not yet available through e-LAB Solutions Suite.

If multiple laboratories with separate CLIA numbers are seeking CAP accreditation, each laboratory must be accredited separately, even if operating within the same institution.
Two laboratories under separate CLIA numbers seeking CAP accreditation at the same address must have separate CAP numbers, and likewise must enroll in separate PT products and not share PT 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 submit the following application materials (see below for Biorepository Accreditation Program application instructions):

- Application forms for general laboratory information, including demographics, personnel, contacts, licensure and certification, affiliated laboratories (for laboratories that qualify to be inspected together), and terms of accreditation.

- Laboratory Section (department) Information forms and associated tests and activities for each section of the laboratory.
  - A “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. (Refer to Appendix B: Guidance in Determining Test Volume.) An address must be provided for any section located at an address different from the physical location address of the main laboratory. Specific test sites must be listed for Point-of-Care Testing sections.
  - The laboratory must provide all tests and activities performed in each section. If submitting a paper application, applicable discipline-specific pages from the Master Activity Menu should be returned with appropriate test activities circled.

- The following supplemental materials must be submitted with the application:
  - Most recent accreditation inspection report (if laboratory was previously accredited by another agency)
• Laboratory Director Questionnaire (Attachment A)
• Organizational chart for the laboratory (not the institution), including names and titles
• Laboratory director’s current curriculum vitae (without the Social Security number). Laboratories that designate a consulting pathologist must also provide a CV for that pathologist. Forensic Drug Testing (FDT) laboratories must provide a CV for the scientific director if the person fulfilling this position is different from the Laboratory Director.
• Current CLIA certificate (or CLIP certificate for United States Department of Defense laboratories) and state licensure certificate, if applicable
• Instrumentation list
• Laboratory Personnel Evaluation Roster (signed and dated by director)
• Travel and Lodging Form
• Individuals serving in the roles of laboratory director, staff pathologists, administrative manager, accreditation contact, quality assurance contact, proficiency testing contact, section director and section supervisors should be directed to maintain their own personal profile information at My Profile on cap.org.

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 FDT Accreditation Program must also submit the following "litigation packet" information:
• A copy of the laboratory’s overall chain-of-custody (COC) procedure with a flow chart illustrating the various steps used by the laboratory to ensure specimen integrity from the initial receipt of a specimen to its final disposition.
• A recent (past 30 days) example of a positive THC-COOH data pack in a litigation format. This should include:
  • Standard operating procedure (SOP) for the screening procedure
  • Screening data for the specimens, calibrator(s), and controls
  • Evidence of review of the screening batch
  • SOP for the confirmation procedure
  • Chromatographic data for the specimens, calibrator(s), and controls
  • Determination of ion ratios
  • Evidence of review
  • Copy of the final report (identity of person tested should be blocked out)
  • Copies of specimen and aliquot internal COC documents

Biorepository Accreditation Program
Before the first on-site inspection, each biorepository must submit the following application materials:
• Application forms that address general biorepository information, including demographics, personnel, contacts, and affiliated biorepositories.
• Laboratory section (department) Information forms and associated activities for each section of the biorepository. The following information must be supplied: section name, responsible personnel, and number of full-time employees (FTEs). For each biorepository section, the
biorepository should complete an activity menu that includes all of the activities performed in that section of the laboratory. These pages may be copied if testing is done in more than one section.

- Supplemental materials, as follows: the director’s curriculum vitae (without the Social Security number); an organizational chart including both names and titles; a floor plan; and travel and lodging information forms.

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

Laboratory Disciplines

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

CAP disciplines/subdisciplines and CMS specialties/subspecialties (when appropriate) will be determined by the selection of activities from the Master Activity Menu. The accreditation letter lists only the disciplines that are reviewed at the time of the on-site inspection. Laboratories that add disciplines and/or analytes after the inspection must notify the CAP either electronically via e-LAB Solutions Suite or in writing; in some cases, additional inspections for added disciplines may be required. (Refer to the Nonroutine Inspections section of this manual).

Activity Menu

The laboratory provides information about its scope of testing and lists all reportable assays and applicable method/scope codes through its activity menu. The information provided is critical, as it is used to customize checklists, determine disciplines for which accreditation is granted, verify proficiency testing enrollment, determine if inspectors with specialty training are required, and determine the laboratory’s annual fee. Accuracy in reporting activity information provided to the CAP is essential. Inaccuracies in providing activities may result in additional fees associated with the need for an additional inspection.

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. All changes should be made directly on the reapplication. Note that the Notification of Change form and Test/Activity Menu Maintenance form included with the reapplication materials are provided to report changes that occur after the reapplication is submitted to the CAP. The following supplemental information must be provided at the time of reapplication: organizational chart, director CV, instrument list, CLIA certificate (CLIP certificate for US Department of Defense laboratories), laboratory personnel evaluation roster, and travel and lodging information. As a reminder, individuals in key roles should be maintaining their own personnel profile information at My Profile on cap.org.
AABB Coordinated Inspection

Laboratories wanting a CAP/AABB coordinated inspection of their transfusion medicine service must indicate that request on the Accreditation Application 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. Due to differences in the timing of CAP and AABB inspection cycles, a coordinated inspection may not be possible for an initial inspection. CAP will alert a laboratory when coordination is not possible for an initial inspection and will work with the laboratory to assist with planning for the next inspection cycle. Refer to the Preparing for the Inspection-AABB Coordinated Inspection sections in this manual for more information.

Accreditation Checklists

- CAP staff determines the checklist used for inspection from the activity menu completed for each laboratory section. Depending on the organization of the laboratory, multiple checklists may apply to any one laboratory section. Supervisors should prepare for inspection using the appropriate discipline-specific checklist(s) and the All Common Checklist. 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: For 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 and the All Common Checklists do 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 used for inspection, regardless of whether another version has been published prior to the inspection. Custom checklists can also be viewed online and downloaded in PDF, Word, or Excel format by accessing CAP e-LAB Solutions Suite.

- Duplicate discipline-specific checklists are required when there is more than one laboratory section performing testing within the same discipline and under the operation of different section directors/supervisors (eg, a separate blood gas laboratory with different supervision than the chemistry section). These checklists are customized based on activities reported for each section and may contain different requirements. The CAP will provide the appropriate quantity of each checklist to the inspector.

- Checklists should not be returned to the CAP headquarters. Refer to Appendix A: CAP Checklist Usage for a detailed explanation of checklist usage.

Returning the Application

Laboratories have two options for completing and returning application materials:
1. Complete the application/reapplication online at cap.org through e-LABs Solutions Suite. All supplemental materials can be uploaded through the online system.
2. Complete the paper application/reaplication and return forms and supplemental materials to:

CAP ACCREDITATION PROGRAMS
COLLEGE OF AMERICAN PATHOLOGISTS
325 WAUKEGAN ROAD
NORTHFIELD, IL 60093-2750
Training the Inspection Team Leader and Team Members

CAP requirements for inspector qualifications 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. 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 complete the appropriate training and online post-test prior to their first inspection. Thereafter, participants are encouraged to review the content that is most relevant to their needs as courses are updated annually.

To fulfill the training requirement, in addition to completing the appropriate course work, participants must successfully pass the post-test. Participants have a total of three opportunities to take and pass the post-test and then claim credit (CME/CE). CME/SAM credit can be applied to the American Board of Pathology (ABP) Self-Assessment Module (SAM) requirements. The AMA requires that participants pass the post-test in an enduring online program to claim credit; if participants do not pass, they cannot claim any credit.
To enroll in team leader or team member training, go to cap.org, click on the Laboratory Improvement tab, then Accreditation. Under Inspector Training and Resources, click on View Training Options and Resources.

Optional Educational Activities

LAP Webinar Series - Focus on Compliance: These LAP presentations assist laboratory professionals in remaining current with accreditation requirements and 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 computer/laptop and Internet access. There is no limit to the number of participants at any one registration site. CE credit is available for each session attended; CME credit is available for specific sessions.

- To register for the LAP Focus on Compliance webinars, go to cap.org, click on the Laboratory Improvement tab, and then Accreditation. Under Accreditation Learning, click on View Courses. NOTE: LAP webinars do not fulfill the training requirement for team leaders or team members.

- To hear previously presented webinars, go to cap.org; log into the e-LAB Solutions Suite; under CAP Accreditation, choose CAP Accreditation Resources and then Educational Resources.

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

- To access these modules, go to cap.org, click on the Laboratory Improvement tab, then Accreditation. Under Inspector Training and Resources, click on View Training Options and Resources.

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 screen assignments, and notification of assignments 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: Unannounced Inspection: Tips for the Laboratory and Inspectors.

Team Leader Qualifications

Team leaders should be:
A peer of the laboratory/biorepository director, with similar status, type of practice, and hospital or laboratory/biorepository size

- Preferably a board-certified pathologist* and a CAP Fellow
- Affiliated currently or recently with a CAP-accredited laboratory/biorepository
- Trained in the inspection process and in team leader responsibilities
- Not engaged in a close personal, family, business, or professional relationship with any personnel in a laboratory/biorepository that he/she will inspect

* A nonpathologist inspector may serve as the team leader for a laboratory that is typically not directed by a pathologist (e.g., 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 the anatomic pathology sections, or supervise the inspection of those sections if performed by a qualified histotechnologist or cytotechnologist (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). The team leader for a biorepository inspection must have the qualifications to be a director of a biorepository. The staff inspector assignment specialist at the CAP headquarters makes these assignments. Refer to the Inspecting Other Types of Laboratories - Staff-inspected Laboratories section of this manual for more information.

**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
  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. Name tags for the team (every team member should wear a name tag while in the host facility)
  11. 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 contiguous United 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 CV
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
  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 (Surgical Pathology and Autopsy) 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. 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, virology, and molecular microbiology), 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, including an explanation of the need for additional inspectors, and faxed to the CAP headquarters at 847-832-8171. The CAP 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 Checklist 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. (Refer to the Preparing for the Inspection section of this manual.)
• 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, 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 requirements in the Laboratory General Checklist.

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.

To arrange the inspection date, the team leader must:
• Contact the laboratory director(s) within two weeks of receiving the Inspector’s Inspection Packet. Contact all directors if special function laboratories are to be inspected in conjunction with the main clinical laboratory. The inspection date must be mutually agreeable to all laboratory directors.
• Ensure that the inspection occurs no more than 90 calendar days before the laboratory’s accreditation anniversary date. A mutually acceptable date is preferable; however, the inspection is scheduled at the convenience of the inspector.
• Notify the CAP’s 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 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 (e.g., histology slides for review) and preliminary instructions regarding availability of documentation (personnel and training records, procedure manuals, proficiency testing results, test validation studies, QC and maintenance records, and a sampling of completed case records [as applicable]). (See an example of the template letter in Appendix D: Sample of Inspection Confirmation Letter to Laboratory Director.)
• 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 send a 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 CAP 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. 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 the US Department of Defense (DOD), Indian Health Service (IHS), and US 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 taxes for inspectors. Inside the US, inspectors should 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.

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 assessor has been assigned, the CAP will provide the name, email address, and telephone number of the AABB assessor to the CAP team leader. The CAP team leader then contacts the AABB assessor to determine if a concurrent inspection can occur.
- When the laboratory’s application/reapplication is complete and the CAP Inspector Packet is sent, the CAP will send to the AABB assessor a packet containing the Transfusion Medicine, Laboratory General and All Common Checklists, an Inspector’s Summation Report (ISR) form, the laboratory director’s CV, an organizational chart, a Personnel Roster (PER), instructions, a letter informing the assessor of the name and telephone number of the CAP team leader, and a return envelope. The AABB assessor should contact the CAP
team leader if communication has not already occurred to determine if a concurrent inspection can occur.

- Due to differences in inspection cycles and dates between the CAP and AABB, a concurrent inspection cannot be guaranteed even when requested.
- If the AABB inspection cannot be concurrent with the CAP inspection, the AABB assessor 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 assessor 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 assessor’s report. The CAP accreditation decision will occur only when inspector findings from both organizations have been submitted to the CAP.

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

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Principles: How to Inspect</td>
<td>29</td>
</tr>
<tr>
<td>How To Inspect Using the Checklist(s)</td>
<td>35</td>
</tr>
<tr>
<td>Using the Team Leader Assessment of Director &amp; Quality Checklist</td>
<td>36</td>
</tr>
<tr>
<td>Meeting With the Laboratory Director</td>
<td>36</td>
</tr>
<tr>
<td>Meeting With the Hospital Administrator/CEO</td>
<td>37</td>
</tr>
<tr>
<td>Meeting With a Representative of the Medical Staff</td>
<td>37</td>
</tr>
<tr>
<td>Meeting With Direct Health Care Providers</td>
<td>38</td>
</tr>
<tr>
<td>Meeting With Clients of Independent Laboratories / Other Meetings</td>
<td>38</td>
</tr>
<tr>
<td>Inspecting Additional Activities, Disciplines, and Laboratories</td>
<td>39</td>
</tr>
</tbody>
</table>

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. R·O·A·D (Read, Observe, Ask, Discover) and Evidence of Compliance (EOC) components are found in each checklist. These tools will 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 with 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 account, 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 list help the inspector understand the type and scope of testing that 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 or emailing a required checklist section to the inspection site).

How to Begin the Inspection: One hour prior to arrival, the team leader should contact 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 earlier than for an announced inspection. This allows enough time to get through security, if applicable, and gives the laboratory sufficient time to locate key personnel and make 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, FDT, and international inspections are announced; the team leader and the facility director determine the date and time for the inspection in advance.

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/techniques; **Ask** probing questions; **Discover** the path of a process—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 provide 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 a sampling of the transfusion reaction workups for the past two years.

**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 written 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 records and observations
- Assess the laboratory’s understanding of the requirements

For example, use questions that begin with phrases, such as:
- “Show me how …”
- “Tell me about …”
- “What would you do if …?”

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. It also avoids staged answers. For example, a question such as “Could you show me the specimen transport policy and describe how you ensure optimum specimen quality?” helps the inspector 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.

Asking laboratory staff questions that can be answered simply by reviewing a chart or record should be avoided. For example, instead of asking, “Are there records 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 your initial review does 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 (eg, 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
  o Appropriate reference ranges
  o Retention of test records
  o Maintaining confidentiality of patient data
  o 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, QC and PT records, instrument maintenance records, and test method validation and verification studies. As the inspector examines procedures and records, 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 must be complete, current, available to staff, accurate, and descriptive of good laboratory practices. The laboratory director or a designee must review them at least biennially. QC and PT records must be complete, reviewed, and show evidence of troubleshooting and error resolution. PT must be performed for all required analytes, and an alternative performance assessment performed for all remaining testing, regardless of test complexity. Records of test method validation or verification studies must be available to the inspector regardless of when the laboratory implemented the test, and be available for at least
two years after the test or method is retired. For each nonwaived test, the laboratory must have data on the test’s accuracy, precision, analytical sensitivity, interferences, analytical specificity, and reportable range, as applicable.

In addition to examining records, 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 are performed using requirements from the Laboratory General and Biorepository Checklists. Inspectors review policies and procedures, the quality management plan, QC records, instrument and equipment maintenance records, and specimen processing records. 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, informed consent, and institutional review board practices. The inspection will also include 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, QC 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 for each inspector to review a representative sampling of analytes or procedures comprehensively than to review the records for 50 tests superficially. Good habits of experienced inspectors also include: review of data selected from the beginning, middle, and end of the period since the last on-site inspection; review of records in the preanalytic (order entry and specimen collection, processing and transport), analytic (procedures, QC, PT, instrument setup, and maintenance), and postanalytic categories (reports, reference ranges, and critical value notification); and if problems are discovered (Discover), a review of similar records for additional analytes. Discovery is a technique to further evaluate areas of concern. “Follow the specimen” and “teach me” are two examples of discovery.

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. Investigation of PT problems should include review of the QC and maintenance records from around the same time interval. If there is evidence of an unacceptable proficiency testing event, records should be reviewed for the subsequent proficiency testing event for that analyte. Closely examine the testing records to confirm that the samples were handled and reported in the same manner as patient specimens (COM.01600) and following laboratory policy and procedure. Determine if any inappropriate actions were taken to ensure an acceptable event score, such as duplicate testing of samples when not indicated in laboratory policy.

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 graded 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 …?”

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 as written or is not being recorded; if there is no record of review or corrective action; or if the procedure is an ineffective or bad laboratory practice. In the situation where records are incomplete, the inspector must judge whether the degree of partial compliance is likely to have adverse effects on test accuracy, patient care, or worker safety. Also, determine if laboratory staff was aware of the inconsistency and if corrective actions were performed. If adverse effects are likely or there are definite patterns (eg, missing temperatures on weekends without corrective actions), 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. For requirements dealing with personnel, proficiency testing, QC/QA, and director oversight, a deficiency must be cited for any non-compliance issue.

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 and checklist requirement phase, followed by the specific manner in which the laboratory is noncompliant, citing specific examples (ie, dates involved, analytes affected, instruments or kits used, name of record or procedure, etc), whenever 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 CAP’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 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 written. The current version must be available to staff and show appropriate approval by the laboratory director. Make notes of any questions you may have or processes you would like to observe as you read the policies and procedures. Quality management (QM) forms and other records should have revision dates or version numbers to verify the current forms are in use.

The checklist requirement 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 forms reflecting rotation among testing personnel

These examples will help the inspector more accurately assess compliance. However, other types of documentation may also be acceptable. The notes provided with some checklist requirements serve as guides to interpret the requirement.

**Verify PT Problems Have Been Resolved:** The PT Performance <100% Report in the inspector’s packet identifies analytes with 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. QC and maintenance records should be thoroughly reviewed, focusing on the time period when any incorrect PT result occurred. Review PT records to confirm that appropriate corrective action was recorded and reviewed by the laboratory director or designee.

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

**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 Preamalytic and Postanalytic Issues:** The inspector may choose a representative specimen and follow the specimen through the laboratory or section, 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, QC and PT records, instrument maintenance records, and
method performance validations or verifications for the last two years, selecting timeframes at the beginning, midpoint, and end of this period. Compare instrument printouts to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

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 recognize and document systemic problems with the laboratory’s QM 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 QM plan, and the laboratory’s relations with the institutional medical staff and administration.

For Biorepository Accreditation Program inspections, the requirements for the assessment of the biorepository director are included in the Laboratory General Checklist. The team leader may choose to interview a member of administration and researchers (users of the biorepository’s services) if available, but this step 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 inspection with 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 (ISR).

The team leader may record information from these interviews in the Part A of the ISR and should cite deficiencies, when appropriate, on the TLC Deficiency page of the ISR.

Meeting With the Laboratory Director

Purpose: To help determine if the laboratory director has sufficient responsibility, authority and involvement in the operations 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 conversations with technical staff, administration, and the CMO may be used to validate the director’s involvement.

The interview is an opportunity to:
• Evaluate the director’s activities as listed in the 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 might serve to resolve (eg, space problems, staffing shortages).

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

For hospital-based laboratories, the team leader 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:** To extend the CAP’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 accreditation programs: education, laboratory improvement, and the establishment of best practices in laboratory medicine based on input from national experts
• The role of PT in the program
• The responsibility of the laboratory director for the overall operation of the laboratory, per the requirements of the CAP’s accreditation programs and CLIA regulations

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.

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:** To 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.

**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:** To 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 or email a customized checklist to the inspector. The inspector must verify that the laboratory is enrolled in appropriate PT 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/Reapplication

Laboratories that perform testing under a different CLIA number or special function laboratories that are under separate administrative and professional direction (e.g., 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
REQUIREMENTS APPLICABLE TO ALL LABORATORY SECTIONS

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements Applicable to All Laboratory Sections</td>
<td>40</td>
</tr>
<tr>
<td>Quality Control</td>
<td>40</td>
</tr>
<tr>
<td>Waived Test Requirements</td>
<td>40</td>
</tr>
<tr>
<td>Instruments and Equipment</td>
<td>41</td>
</tr>
</tbody>
</table>

Note: Checklists are frequently revised and requirements may change. This may cause information in this manual to be inconsistent with the most recent checklist edition, which contains 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.

Many requirements for quality control and instruments and equipment are applicable throughout the laboratory.

For additional requirements specific to each individual discipline, consult the discipline-specific sections of this manual.

Quality Control (QC): The QC checklist requirements are designed to determine if QC procedures are clearly defined, if the QC program appropriately monitors test performance, and if corrective actions are taken when necessary.

For waived testing, manufacturer’s instructions for QC must be followed. For non-waived quantitative testing, at least two levels of QC must be performed each day of testing in most cases. For nonwaived qualitative testing, positive and negative controls must be performed each day of patient testing. Use of internal control processes (e.g., electronic, procedural, or built-in) is acceptable as part of a QC plan, but requires the use of an individualized quality control plan (IQCP) if it is used in lieu of external QC materials to meet daily QC requirements for nonwaived testing. Refer to the Inspecting the Laboratory Sections – All Common section in this manual for more information on IQCP.

The laboratory must determine valid acceptable ranges for QC and record corrective action when the defined limits are exceeded. 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. The laboratory must follow manufacturer’s instructions and/or state regulations if those are more stringent than those of the CAP.

Waived Test Requirements: Certain checklist requirements are different for waived tests and nonwaived tests. The checklist contains explanatory information to indicate the applicability of the requirements based on the complexity of testing. The current list of tests waived under CLIA may be found at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.
Manufacturer’s instructions for FDA-cleared or approved waived tests must be followed as written. If the instructions are modified, the test becomes subject to checklist requirements for high complexity testing, including personnel qualifications, competency assessment, method performance specifications, PT (nonwaived program enrollment), comparability of instruments/methods, QC, reagents, instrument maintenance and function checks, and calibration and analytical measurement range verification.

For waived tests, checklist requirements relating to the following are not required (unless listed in the manufacturer’s instructions):
- Lot-to-lot reagent checks
- Comparability of instruments and methods (between waived instruments or waived and main laboratory instruments)
- Calibration, calibration verification, and AMR verification

Checklist requirements for PT, quality management, procedure manuals, specimen handling, results reporting, and safety are the same for both waived and nonwaived tests.

**Instruments and Equipment:** General instrument and equipment requirements are found in most discipline specific checklists, and address glassware, pipettes, centrifuges, and analytical balances. Requirements for routine maintenance and function checks, thermometers, and temperature-dependent equipment are in the All Common Checklist.

- **Glassware:** Volumetric flasks must be of certified accuracy (i.e., Class A category of the National Institute of Standards and Technology). 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.
- **Pipettes (fixed-volume, adjustable, and micropipettes):** Check pipettes and dispensers for accuracy of calibration and reproducibility (by colorimetric, gravimetric, volumetric, or other means) before being placed in service, and record results. Verify accuracy and reproducibility at laboratory-defined, periodic intervals. Limit the use of dispensers to measurements not requiring volumetric accuracy.
- **Analytical balances:** 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). Records of the accuracy checks must be maintained.

Consult the discipline-specific checklists and All Common Checklist for instrument and equipment requirements other than the general requirements discussed here.
INSPECTING THE LABORATORY SECTIONS
LABORATORY GENERAL (GEN)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ways the Discipline-Specific Inspector Can Assist the Laboratory General Inspector</td>
<td>42</td>
</tr>
<tr>
<td>Quality Management</td>
<td>43</td>
</tr>
<tr>
<td>Personnel</td>
<td>43</td>
</tr>
<tr>
<td>Space and Facilities</td>
<td>44</td>
</tr>
<tr>
<td>Specimen Collection</td>
<td>44</td>
</tr>
<tr>
<td>Laboratory Transport Services</td>
<td>45</td>
</tr>
<tr>
<td>Personnel Competency Assessment</td>
<td>45</td>
</tr>
<tr>
<td>Computer-Generated Reports</td>
<td>45</td>
</tr>
<tr>
<td>Review of Results</td>
<td>46</td>
</tr>
<tr>
<td>Confidentiality and Read-Back of Patient Orders and Reports</td>
<td>46</td>
</tr>
<tr>
<td>Record and Specimen Retention</td>
<td>46</td>
</tr>
<tr>
<td>Self-Inspection Records</td>
<td>46</td>
</tr>
</tbody>
</table>

The Laboratory General Checklist covers the entire laboratory and is used with each inspection. Issues such as quality management, personnel, specimen collection, computer function, inventory control, safety, and physical facilities 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) and discuss the findings with the laboratory general inspector at lunch or before the presummation 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 can 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. 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 benchtop space to open a procedure manual, storage that is underfoot, or blocked hallways.

**Quality Management:** The laboratory must have a written quality management (QM) 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 laboratory director. In laboratories that are part of a larger institution (eg, a hospital), the laboratory QM program must be integrated with the institutional program.

The laboratory must have a written policy 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 program 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.

**Personnel:** Instructions for sampling and evaluating laboratory personnel records are included in the Team Leader section of the Inspector’s Inspection Packet, and are 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 for each employee must include all of the following:
• Summary of training and experience
• Copy of an academic diploma, transcript, or primary source verification report demonstrating that the employee meets required educational qualifications
• Laboratory personnel license, if required by the state
• Certification if required by the state or employer
• Description of current duties (may be generic to a position)
• Records of continuing education
• Records of radiation exposure where applicable
• Work-related incident and/or accident records
• Dates of employment
For non-US trained personnel, an evaluation of education and experience by a foreign credentialing agency 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. Discuss suggestions related to staffing levels and pathologist coverage issues directly 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 qualifications and responsibilities of supervisory personnel, including technical supervisors, general supervisors, technical consultants, and clinical consultants, are defined in the Laboratory General Checklist. Refer to the Laboratory Personnel Evaluation Roster for a listing of individuals filling these roles. The laboratory director must delegate the duties to be performed in writing and ensure that they are performed in a satisfactory manner.

Requirements for laboratory directors are found in the Team Leader Assessment of Director and Quality Checklist.

The biorepository director must:
- Meet the qualifications found in the Standards for Biorepository Accreditation.
- Have defined the appropriate training, experience, and/or educational credentials. The director’s experience and qualifications must meet the institutional policy for the degree of responsibility acceptable to operate and manage the scope of the biorepository.
- Have sufficient authority to implement the Standards.
- Meet the requirements listed in the Laboratory General Checklist.

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: Proper collection and handling of specimens 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, visit a collection site to check for the availability of the specimen collection instructions (paper manual or electronic). The inspector must review training records to confirm that all laboratory personnel performing patient blood collection have been trained in the selection and use of equipment, supplies, and collection techniques.

The individual collecting the specimen must positively identify the patient before collecting a specimen. The inspector must verify that there is a consistently followed procedure 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 in the presence of the patient, and not deferred until a later time.

The laboratory director must approve the specimen collection/handling manual before implementation and ensure that it is reviewed at least every two years by the laboratory director or a designee. 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 existing procedures before implementation.

**Laboratory Transport Services:** For 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, there must be a tracking system to ensure that all specimens submitted to the testing 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 a means to improve the performance of clients or offices that frequently submit specimens improperly.

Federal and international regulations mandate the proper packaging and transportation of infectious substances, also called “etiologic agents.” Specific requirements are set forth by the US Public Health Service, US International Air Transport Association, US Department of Transportation, and US Postal Service. These requirements 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 three years. Training requirements do not apply to personnel sending samples via private couriers.

**Personnel Competency Assessment:** The inspector will look for records indicating that the laboratory/biorepository has assessed the competency of each person to perform his or her assigned duties annually. A semiannual evaluation is required during the first year of an individual’s duties for nonwaived personnel. The laboratory/biorepository must have a corrective action plan to retrain and reassess employee competency when problems are identified with employee performance. The inspector will look for evidence that the laboratory/biorepository reassessed competency and found it acceptable after implementation of a corrective action plan.

The laboratory director may delegate, in writing, the assessment of competency to other qualified individuals. The qualifications to assess competency of testing personnel is based on the complexity of the testing performed. The inspector will confirm the qualifications of the individuals assessing competency.

**Computer-Generated Reports:** A laboratory information system (LIS) located on site must be clean, functional, and secure, with adequate ventilation and firefighting equipment. The laboratory must have approved, written procedures for operators and laboratory staff, including a downtime process. The laboratory must have records of hardware and software modifications, and must validate that the system performs as expected. Training, maintenance, calculation verification checks, and interface verification must be performed and recorded. The system must have data backup capabilities.

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 include algorithm decision rules to detect absurd values and results requiring
manual review. There must also be a process for rapid suspension of autoverification in the event of a problem. The autoverification process must be validated initially and verified at least annually and when there are changes that may affect autoverification logic.

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.

**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. There is no requirement for secondary daily review of patient test results.

**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 referral laboratories.

**Record and Specimen 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, QC records, PT records, instrument and equipment maintenance 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 as 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.

Patient specimens must be stored under appropriate conditions to ensure their integrity. Serum and body fluid specimens (excluding urine) must be retained for at least 48 hours. Blood films, permanently stained body fluid slides, and microbiology slides must be retained for at least seven days. Additional detailed requirements or recommendations are found in section-specific checklists.

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 F: Retention of Laboratory Records and Materials for complete information on record retention.

**Self-Inspection Records:** Laboratories must perform a self-inspection each year that an on-site inspection by the CAP does not take place. The laboratory is given 60 calendar days (from receipt of materials) to complete the self-inspection and return the signed forms indicating completion of the self-inspection to the CAP. If deficiencies are found, the laboratory must record corrective action for each deficiency. Records of the performance of the self-inspection, deficiencies identified, and corrective actions must be retained for review by the next on-site
inspection team upon request. The inspectors will evaluate the effectiveness of the corrective action taken.
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. 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 the portion(s) of the laboratory for which he/she is responsible.

General Safety: Written safety policies and procedures must be available to all employees. Instruction in safe work practices must be included 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 workplace fatalities must be reported to the Occupational Safety and Health Administration (OSHA) within eight hours and all work-related in-patient hospitalization, amputation, or loss of an eye must be reported within 24 hours. Evaluations of occupational injuries or illnesses that require medical treatment or result in time lost from work must be incorporated into the laboratory’s QM program to avoid recurrence. This includes every needle stick or sharps injury. OSHA requires employers to select safer needle devices as they become available and involve employees in identifying and choosing the devices. The OSHA standard requires employers to maintain a log of injuries from contaminated sharps. Inspectors will inquire 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 and approve all changes to safety policies and procedures before implementation. Periodic reviews of safe work practices to reduce hazards must be conducted at least annually.
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 (AFE) 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 (SCD); 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 needs to 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 records that the local fire authorities have approved the current arrangement.

Fire safety training must be performed for all new employees, with a fire safety review conducted at least annually for all employees. While exit fire drills are not required, physical evaluation of escape routes must be performed annually. Class B portable fire extinguishers must be located in all areas where flammable or combustible liquids are stored or handled. If the fire safety plan includes laboratory staff use of portable fire extinguishers, records that all personnel have been properly trained must be retained. 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 must be in amounts reasonable for the laboratories. The Laboratory General Checklist specifies the US maximums 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 exempt. If tasks are delegated to biomedical and electrical engineers, records must be present on the inspection day, or a deficiency will be cited.

Chemical Hazards: The laboratory must evaluate the hazards associated with all chemicals present and have information concerning the hazards transmitted to employers and employees. 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. Safety data sheets (SDS) must be on file for each hazardous chemical. It is acceptable for SDS information to be electronically available to users, rather than in book format; there is no requirement for paper-based information. However, the SDS 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

---

1 29 CFR 1910,1200
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, written Chemical Hygiene Plan (CHP)\(^2\) 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 SDS (and other pertinent references), and the medical procedures to be followed if contact or overexposure occurs. Monitoring of vapor levels of formaldehyde and xylene are 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. Provisions must be in place to include training on the elements of the CHP to employees.

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.\(^3\) (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. There must be records showing an evaluation of the chemicals in use, and specific handling requirements must be defined for the handling of hazardous chemicals. If records are not available showing that chemicals were evaluated, a deficiency should be cited.

Personal protective equipment (PPE) appropriate to each hazardous task must be provided, with its use mandated where appropriate. Such items include face shields, aprons, and gloves constructed of materials appropriate to the type of chemical handled. Plumbed eyewash fountains or self-contained units must be present and must be checked weekly. It is a deficiency if this equipment is present, but access to it is obstructed. Chemical fume hoods must be checked annually for proper function.

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

\(^2\) 29 CFR 1910.1450
\(^3\) 29 CFR 1910.1001-1047
It is 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 of nonlatex or powder-free latex gloves to prevent hypersensitivity reactions to latex proteins is required. To prevent the transmission of potentially infectious agents, OSHA requires decontamination of hands after glove removal using an effective antimicrobial method. 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.

Written procedures detailing procurement, transportation, and handling of patient specimens (blood, body fluids, and tissue) must be in place to ensure that all specimens are submitted in an appropriately labeled and well-constructed container with a secure lid that prevents leakage during transport. 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 written 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, December, 2009). 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. The inspectors will review the records for annual BSC checks to ensure that the inspection included filter checks, flow rate measurements, and tests for seam integrity.

**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, must be discarded in puncture-resistant containers with tightly fitted lids and appropriately labeled.

The inspector will review the laboratory’s written policies and procedures for waste disposal and cite the laboratory if the manual lacks appropriate detail or omits important items. Inspectors will ask technologists questions about the segregation of wastes by hazard class at the point of

---

4 HHS publication, 1993 stock #017-040-00523-7
generation to determine whether they understand the facility's policy. The inspector will visit the collection point at which wastes are collected 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 is 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). These policies and procedures should be developed in conjunction with the institutional radiation safety office and in compliance with any state regulations. The policies and procedures should distinguish between low-radioactivity specimens, such as sentinel lymph nodes, 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, spill of hazardous volatiles (internal disaster), tornado, earthquake, or other mass-casualty situation (external disaster). The form that this portion of the safety manual takes must specifically address the needs of the laboratory. There must be a written, comprehensive, and workable evacuation plan specific to the laboratory that covers all employees, patients, and visitors, and must address the special needs of persons with disabilities. Evacuation routes must be clearly marked (posting evacuation routes is optional) and emergency lighting must be adequate for the safe evacuation of the laboratory.

**Ergonomics:** There must be a written ergonomics program to prevent musculoskeletal disorders (MSDs) in the workplace through prevention and engineering controls. The program may include training of employees about risk factors, identifying physical work activities or conditions of the job commonly associated with work-related MSDs, and recommendations for eliminating MSD hazards. 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.
## INSPECTING THE LABORATORY SECTIONS
### ALL COMMON (COM)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist Usage</td>
<td>53</td>
</tr>
<tr>
<td>Preparing to Inspect</td>
<td>54</td>
</tr>
<tr>
<td>Proficiency Testing (PT)</td>
<td>54</td>
</tr>
<tr>
<td>PT Enrollment and Participation</td>
<td>54</td>
</tr>
<tr>
<td>PT Enrollment for Multiple Matrices</td>
<td>55</td>
</tr>
<tr>
<td>PT Performance</td>
<td>55</td>
</tr>
<tr>
<td>Investigating PT Failures and Biases</td>
<td>56</td>
</tr>
<tr>
<td>Corrective Action Following a PT Failure</td>
<td>57</td>
</tr>
<tr>
<td>Quality Management – General Issues</td>
<td>57</td>
</tr>
<tr>
<td>Procedure Manual</td>
<td>58</td>
</tr>
<tr>
<td>Critical Results</td>
<td>59</td>
</tr>
<tr>
<td>Reagents</td>
<td>59</td>
</tr>
<tr>
<td>Instruments and Equipment</td>
<td>59</td>
</tr>
<tr>
<td>Thermometers and Temperature-Dependent Equipment</td>
<td>60</td>
</tr>
<tr>
<td>Test Method Validation and Verification</td>
<td>60</td>
</tr>
<tr>
<td>Method Performance Specifications</td>
<td>60</td>
</tr>
<tr>
<td>Reference Intervals</td>
<td>61</td>
</tr>
<tr>
<td>Individualized Quality Control Plan</td>
<td>61</td>
</tr>
<tr>
<td>Inspection Resources</td>
<td>62</td>
</tr>
</tbody>
</table>

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

**Checklist Usage:** The All Common (COM) Checklist is a core set of requirements that apply to all areas performing laboratory tests and procedures. It is made up of requirements addressing proficiency testing, general quality management, specimen collection and handling, procedure manuals, critical result reporting, reagents, instruments and equipment, test method validation and verification, reference intervals, and the individualized quality control plan (IQCP).

Each section of the laboratory is assigned its own COM Checklist. In some instances, the same requirement exists in both the COM checklist and the discipline-specific checklist, but with more
specificity in the discipline-specific checklist. In these situations, the discipline-specific requirement takes precedence.

**Preparing to Inspect:** The inspector must be familiar with both the All Common and the Laboratory General Checklists along with the discipline-specific checklists for which he/she is responsible. 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 (PT)**
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 through e-LAB Solutions Suite on cap.org or the CAP Surveys Catalog Analyte/Procedure Index.) There are three parts to the accreditation program’s PT compliance process: confirmation of enrollment, participation, and successful performance monitoring. In general, the CAP Accreditation Program does not require PT for calculated analytes. However, there are a few exceptions that require PT enrollment (eg, Hemoglobin estimated, Hematocrit calculated, and INR).

Any questions or requests for more information may be directed to the Proficiency Testing Compliance Department at CAP headquarters at 800-323-4040 ext. 6052.

**PT Enrollment and Participation:** The CAP monitors PT enrollment and participation continuously to ensure that accredited laboratories are enrolled and participate in PT as appropriate. Accurate monitoring is dependent on the laboratory maintaining its Activity Menu. The Activity Menu must reflect the laboratory’s current testing, including the removal of discontinued tests. Participation in a CAP-accepted PT program is required for most analytes/tests. Approval as a PT provider by the CMS under CLIA does not automatically constitute acceptance by the CAP for purposes of accreditation.

If enrollment in a CAP-accepted PT program (see Appendix G: Glossary of Terms) is not required for a particular analyte/test, the inspector must verify that the laboratory has records of alternative performance assessment twice per year to assess the analytic performance for that test. In cases where PT is not available due to oversubscription from all CMS approved providers, the laboratory also must perform alternative performance assessment. This alternative assessment should use the same number of challenges as the missed event. Alternative performance assessment may include:

- Participation in a PT program (graded or educational) supplied by the CAP or other provider
- Split sample analysis with another laboratory
- Split sample analysis with an established in-house method, assayed material, and regional pools
- Clinical validation by chart review, or other suitable and documented means

Alternative performance assessment that allows for comparison of results with an external reference (PT programs, split sample with external laboratory, split sample with regional pool) may provide more information than split sample analysis using internal methods. In all cases, the laboratory must define acceptable criteria for alternative performance 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 addition to establishing criteria for alternative performance assessment, the laboratory must troubleshoot any results that fall outside the
expected range of acceptability. The laboratory director (or designee) is expected to review and sign off on these results just as with any formal PT evaluation.

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.

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

**PT Enrollment for multiple matrices:** In general, PT enrollment is not required for both serum/plasma and whole blood matrices. If separate PT programs are available for both serum/plasma and whole blood matrices, laboratories may choose to enroll only in the PT program for what is considered the primary sample type in the laboratory. Alternative performance assessment must be performed semi-annually for the other matrix. Laboratories may choose to enroll in separate PT programs for both matrices, which would fulfill alternative assessment requirements.

Urine and body fluids are unique matrices, usually with different calibrators, reagents, reference ranges and/or clinical decision-making values than serum/plasma/whole blood. The laboratory must enroll in a PT program specific for urine or body fluid matrices if PT is required for the test/analyte.

**PT Performance:** PT performance monitoring is a process that looks for trends of unsatisfactory performance continuously across all testing events. If the laboratory has a second unsatisfactory performance for the same analyte/subspecialty (unsuccessful performance), the CAP’s PT Compliance Department will require the laboratory to provide records of corrective action. In the case of repeat unsuccessful PT performance for a CLIA regulated analyte, the laboratory will be directed to cease patient testing for six months per CLIA requirements. If the laboratory refuses to cease testing, its accreditation will be in jeopardy. Before the laboratory can resume testing, it will be required to present a plan of corrective action and demonstrate acceptable performance on reinstatement PT. The inspector uses PT performance to pinpoint areas for a more rigorous review during the on-site inspection.

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. Interlaboratory communication regarding PT samples with personnel outside the laboratory’s CLIA number is prohibited until after the deadline for submission of data to the PT provider. 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. PT must be performed and reported at the physical location of the laboratory; this includes pathology review of abnormal blood smear PT and submission of PT results to the PT provider. If the pathologist cannot review the PT slide onsite, the laboratory must submit a PT result indicating the test is not performed on-site, and would refer to another laboratory. The laboratory 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 performance assessment procedures. 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.

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 records in the personnel files. Staff performing PT testing and the laboratory director or designee (qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing) must physically sign the attestation form provided with each PT mailing, even if results are entered electronically on cap.org.

Replicate analysis of any proficiency sample is acceptable only if patient/client specimens are routinely analyzed in the same manner. Otherwise, replicate analysis may only be performed after the due date for return of results to the PT provider. If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method.

The inspector will ask to see specific documentation of PT 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, and verification of the analytical measurement range. There must be records 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 each unacceptable PT result, 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 (as defined in the laboratory policy). The review must also confirm that patient/client results were not affected during the period of time the PT was unacceptable.

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 have a written procedure for assessing its performance on PT challenges that were intended to be graded but were not. Suggestions for investigating non-graded PT results are given in Appendix H: Accreditation Requirements When a PT Result is Linked to an Exception Reason Code. The inspector will affirm that formal PT or alternative performance assessment is performed for every test performed on patient samples, and that all corrective actions are appropriate.

**Investigating PT Failures and Biases**: When investigating PT failures of biases, the following actions may be taken:
• Check reporting forms and records of sample preparation and testing for possible nonanalytic (e.g., clerical) and analytic errors.
• Review QC performance, instrument calibration, and reagent performance prior to, during, and after the time of PT performance.
• Verify that the PT material was processed in the correct instrument mode and reported in the correct units.
• Investigate consistent biases or trends (as defined in the lab’s policy on PT review).
• Contact the instrument/reagent manufacturer for assistance.
• Repeat the PT challenge, if possible, using a different reagent lot or instrumentation system.
• Confirm that patient/client results were not affected during the period of time the PT was unacceptable.

Corrective Action Following a PT Failure: The laboratory must have records of corrective action for each unacceptable PT result. Depending on the cause of the failure, some actions that may be taken as part of the corrective action may include:
• Repeat instrument function or testing system verification.
• Modify the frequency of calibration.
• Revise or replace the analytic procedure.
• Design a process to double check clerical entries prior to submitting PT results. (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.)
• Ensure all staff know when PT kits are due to arrive and when results are due.
• Retrain testing personnel in the proper procedures for sample preparation, testing, and reporting.
• Maintain clear records of all corrective actions taken.

For assistance with troubleshooting PT failures, refer to the CAP’s PT/External Quality Assurance Toolbox available through e-LAB Solutions Suite.

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

Quality Management – General Issues: A laboratory’s written quality management program must define the processes used to ensure quality throughout all phases of the testing process. Monitoring the analytic and postanalytic processes includes the need to detect and correct significant clerical and analytic errors, and unusual results in a timely manner.

For the monitoring of instrument and equipment functioning, maintenance and function check records must be reviewed at least monthly. If a laboratory uses more than one nonwaived method or instrument for a given analyte, the methods must be checked against each other at least twice a year for comparability of results. The use of human samples, rather than stabilized control materials is preferred; however, the checklist describes the acceptable use of other types of materials.
Specimen Collection and Handling: Specimen collection procedures must be available for all testing, including methods for proper patient identification, patient preparation, specimen labeling, preservation, and transport. Procedures may be available in paper or electronic form.

Checklist requirements are defined for the proper labeling of primary and secondary specimen containers. Primary specimen containers must be labeled with two patient-specific identifiers, with some limited exceptions defined in the checklist, such as trauma situations or de-identified research specimens. A secondary specimen container is any derivative of the primary specimen used in subsequent phases of testing. A single unique identifier may be used to label materials derived from the primary specimen for use during processing or testing. The identifiers used must provide reliable identification and be linked to the full particulars of patient identification, collection date, specimen type, etc. Additional requirements are defined for histology specimens, to include identification of tissue, blocks, and slides to the case and additional descriptive numbers or letters as appropriate.

Procedure Manual

Each section of the laboratory must have a complete procedure manual in a paper-based, electronic, or Web-based format available to, and used by, personnel at the workbench or in the work area. Elements of the procedure manual should include the following, as applicable: test principle, clinical significance, specimen type(s), requirements for specimen collection and handling, required reagents, calibration, QC, procedural steps, calculations, reference intervals, and interpretation. The specific style and format of procedure manuals are at the discretion of the laboratory director.

The inspection team must review a sampling of procedures for completeness, laboratory director approval, and review. 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 description 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. QC materials and acceptance criteria, reference intervals, critical values, and reportable ranges are aspects of a procedure that often result in customization by the individual laboratory.

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 if electronic versions are readily available to all personnel and personnel have been trained on how to access them. Such electronic versions are subject to proper document control (ie, only authorized persons may make changes, changes are dated/signed [manual or electronic], and there are records of biennial review). Records of review by a secure electronic signature are desirable, but not required.
There must be records 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, a designee must be specified in writing.** For new and significantly changed procedures, the review/approval 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 a sufficient record that each procedure has been reviewed. A signature or initials on each page of a procedure is not required.

**Critical Results**

Criteria for immediate notification of a physician or other clinical personnel responsible for patient care regarding critical tests (e.g., glucose, potassium, calcium) must be established. These criteria can be located 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.

The laboratory must have a policy for the verification “read-back” of critical values that are communicated verbally or by phone.

**Reagents**: For waived tests, reagents must be handled and stored according to manufacturer instructions. For nonwaived tests, 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. Precautionary labels (or readily accessible signs, etc) should be present for reagents that are hazardous chemicals.

The laboratory must use components of reagent kits only within the same kit 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. Examples of suitable reference materials may include previously tested patient samples, QC products provided by the manufacturer with method and reagent specific target values, and QC materials with peer group established means. For quantitative tests, reagent confirmation of acceptability is performed most reliably by assaying the same patient specimens with both the old and new reagent lots. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative sample from the old reagent lot against the new reagent lot.

Reagents must be stored as recommended by the manufacturer. Temperatures must be recorded daily, as applicable. Temperature ranges must be within the manufacturer guidelines and corrective action must be recorded if temperatures fall outside established ranges. The laboratory must not use reagents after their stated expiration date.

**Instruments and Equipment**: A variety of instruments and equipment are used to support the performance of analytic procedures. Examples of equipment include, but are not limited to centrifuges, microscopes, incubators, heat blocks, refrigerators, freezers, biological safety cabinets, fume hoods, glassware, and pipettes.
For instruments used to perform waived testing, the laboratory must follow the manufacturer’s instruction for instrument and equipment maintenance and function checks. For all other testing, the performance of instruments and equipment is verified upon installation and after major maintenance or service to ensure that the instruments are functioning as expected. Written procedures for startup, operation, and shutdown of instruments are required. Maintenance and function checks must be performed, with records maintained for all instruments and equipment following a defined schedule (at least as frequent as specified by the manufacturer). If no frequency is provided by the manufacturer, the laboratory must establish a schedule that reasonably reflects the workload and specifications of its equipment. The laboratory is also responsible for additional instrument and equipment requirements found in the discipline-specific checklists, as applicable.

**Thermometers and Temperature-Dependent Equipment:** An appropriate thermometric standard device of known accuracy (certified to meet NIST standards or traceable to NIST Standards) must be available to check all noncertified thermometers against before being placed into service and as defined by the laboratory policy. Inspectors will confirm that thermometers in use either have current certificates of accuracy or have been checked against an appropriate thermometric standard device.

The temperatures of all temperature-dependent equipment, such as refrigerators, freezers, and incubators, must be checked each day of use. Items such as water baths and heat blocks used for procedures need only be checked on days of patient/client testing. Acceptable limits for all temperature-dependent equipment must be defined in accordance with manufacturer’s instructions, with corrective action performed if limits are exceeded.

**Test Method Validation and Verification:** The laboratory director, or designee meeting CAP director qualifications, must approve each test for use prior to use in patient testing

- For **waived** instruments and methods, the laboratory must follow manufacturer’s instructions for the introduction of instruments and devices and have records showing that the director or appropriate designee has approved the test for use.
- For **nonwaived** testing, the laboratory must establish or verify the method performance specifications and there must be an evaluation of the study (accuracy, precision, etc.) signed by the director or appropriate designee prior to use in patient testing to confirm the acceptability of the data and to approve each nonwaived 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, including instruments of the same make and model and temporary replacement instruments. For each nonwaived test, the laboratory **must** have data for the validation or verification of the applicable method performance specifications (accuracy, precision, analytical sensitivity, interferences, analytical specificity, and reportable range, as applicable). The validation or verification must occur in the location in which testing will be performed. If an instrument is moved, the laboratory must verify the method performance specifications after the move to confirm that the test system was not affected by the relocation process or due to changes in environment. 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.
For a laboratory subject to US regulations for unmodified US Food and Drug Administration (FDA)-cleared/approved tests, the laboratory may use information from manufacturers or published literature, but the laboratory must verify such outside information on accuracy, precision, and reportable range. For tests that are not FDA-cleared/approved, or for FDA-cleared/approved tests modified by the laboratory, the laboratory must establish accuracy, precision, analytical sensitivity, interferences, and reportable range, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable.

Laboratories not subject to US regulations must verify or establish accuracy, precision, analytical sensitivity, analytical specificity (including interfering substances), and reportable range for each test. Laboratories may use information from manufacturers, published literature, or studies performed in other laboratories, but should verify outside information, whenever practical.

The checklist defines additional requirements for validation and reporting that apply to laboratory-developed tests (LDTs) and modified FDA-cleared/approved tests. For purposes of interpreting the checklist, an LDT is defined as follows: A test used in patient management in which it was developed wholly or in part; and 2) The test is neither FDA-cleared nor FDA-approved.

Tests that are taken out of production for a time (eg, tests done in support of research protocols or seasonal testing such as influenza testing) are considered “intermittent 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 performance assessment, as applicable, is suspended. To bring the test back into production the laboratory must meet the following criteria:

• PT or alternative performance 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

Reference Intervals: The laboratory must establish or verify 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.

Individual Quality Control Plan (IQCP): Laboratories may implement an IQCP to customize the QC performed for eligible tests, instruments, and devices used based on the laboratory’s own risk analysis. After January 1, 2016, laboratories performing external control materials less frequently than the limits defined in the CLIA regulations and CAP Checklists must either implement an IQCP or perform QC following the defined minimum limits. Laboratories may not perform QC less frequently than indicated in the manufacturer's instructions.

Eligibility for use of an IQCP is limited to testing meeting all of the following criteria:

• Nonwaived tests that employ an internal (electronic/procedural/built-in) QC system
  ○ Exception: Microbiology media and reagents used for microbial identification and susceptibility testing may implement an IQCP as defined in the checklist
• Tests performed in specialties other than Anatomic Pathology and Cytopathology
  ○ Exception: If an Anatomic Pathology or Cytopathology test can be assigned to a different CMS subspecialty, it may qualify.
If a laboratory is located in a state that does not accept IQCP as an option for reducing the frequency of external QC, the laboratory must follow the state regulations and perform external QC following the frequency defined in the state regulations and CAP checklists.

Laboratories implementing IQCP must be in compliance with all components of IQCP including risk assessment, QC plan, and quality assessment monitoring. Risk assessment records must demonstrate that potential sources of error were evaluated encompassing all phases of the testing process and components of the test, including reagents, environment, specimen testing personnel, and test system. The risk assessment process must include evaluation of laboratory-specific data and involve a representative subset of testing personnel. The QC plan must be approved by the laboratory director and define the number, type, and frequency of QC, and criteria for acceptable performance. The laboratory director may not delegate this duty. Ongoing quality assessment monitoring must be performed to ensure that the QC plan is effective in mitigating identified risks, including reapproval of the QC plan by the laboratory director or designee at least annually. If failures are identified in one or more components of the QC plan, the laboratory must investigate the cause and consider if modifications are needed to the QC plan to mitigate potential risk.

**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.
### INSPECTING THE LABORATORY SECTIONS

#### ANATOMIC PATHOLOGY (ANP)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Management</td>
<td>64</td>
</tr>
<tr>
<td>Quality Control</td>
<td>64</td>
</tr>
<tr>
<td>Digital Image Analysis</td>
<td>66</td>
</tr>
<tr>
<td>Safety</td>
<td>66</td>
</tr>
<tr>
<td>Results Reporting</td>
<td>67</td>
</tr>
<tr>
<td>Autopsy Pathology</td>
<td>67</td>
</tr>
<tr>
<td>Electron Microscopy</td>
<td>67</td>
</tr>
<tr>
<td>In Vivo Microscopy</td>
<td>67</td>
</tr>
</tbody>
</table>

*Inspection of anatomic pathology is not limited to the contents of the Anatomic Pathology Checklist, but includes all applicable portions of 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 Applicable to all Laboratory Sections.*

The Anatomic Pathology Checklist covers general anatomic pathology services, including surgical pathology, intraoperative consultation, Mohs services, histology, immunohistochemistry, immunofluorescence, in situ hybridization (ISH), digital image analysis, autopsy pathology, circulating tumor cell analysis, in vivo microscopy, and electron microscopy. The inspector is expected to evaluate all aspects of QC and quality management in the various sections of anatomic pathology. The inspector will consider procedural and technical activities (process or QC), issues related to the professional role of the pathologist (quality management), and an evaluation of the quality of the diagnostic report (features of both QC 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*).

During the on-site inspection, the inspector will 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.

While performing the inspection, 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.

**Quality Management (QM):** The checklist defines requirements for components that are integral to the laboratory’s quality management program. Such a program must include appropriate combinations of activities, such as the use of intra- and extra-departmental consultations, circulation of diagnostic material (random or by case type), feedback on the quality of specimens submitted to pathology and on the quality of histologic preparations, evaluations of disparities between the intraoperative consultation and final pathology diagnosis, periodic review of completed surgical pathology reports, evaluation of professional competency, and participation in self-assessment and performance improvement programs.

**Quality Control (QC):** 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 (QC) 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. The Cytopathology Checklist must be used if a cytotechnologist is screening FNA specimens or evaluating FNA specimens for adequacy.

Review of the quality of surgical pathology reports is considered under QC. 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 must have a mechanism to correlate the results of specialized studies (e.g., electron microscopy, immunohistochemistry, nucleic acid probes, cytogenetics, etc.) with the morphologic diagnosis, and to **reconcile potentially conflicting data,** when appropriate.

**Histology:** QC items include evaluation of procedure manuals, histologic preparations, special stains, instruments, and equipment. Requirements pertaining to immunohistochemistry are included.

There are several key areas to focus upon during the inspection of immunohistochemistry (IHC), including the oversight functions of the responsible pathologist. The inspector must ensure that there are records of corrective action and pathologist review of QC 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 must 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). Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.

If the laboratory is engaged in IHC for predictive markers such as HER2 or ER/PgR, the report must include information on specimen processing, the antibody clone, and the scoring method used. If the laboratory performs HER2 or ER/PgR testing, either by immunohistochemistry or by 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, it must send the IHC PT slides to that laboratory for processing only, and interpret the slides as per usual. However, any laboratory that performs HER2 testing by in situ hybridization (ISH) interpretation only may not send PT samples to another facility for hybridization. Laboratories that only interpret HER2 by ISH are required to perform alternative performance assessment to demonstrate that their testing process and interpretation are accurate. These data must be reviewed during on-site inspections.

For HER2 and ER/PgR testing, 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 have a written procedure to ensure specimen fixation time.

The inspector must assess the quality of the immunostains by direct review of immunostained slides. Sample pathology reports representative of the reporting format used for immunostains must be reviewed along with the slides. The inspector must verify that the reports contain all required elements specified in the checklist.

The inspector must 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 post-analytical 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 ISH. The checklist section on digital image analysis does not apply to laboratories that are imaging slides for manual scoring or review by an individual.

There must be records that the system has been validated, including definition of acceptable specimen conditions. If the system is not FDA-cleared/approved (or is FDA-cleared/approved but modified by the laboratory; for instance, use of a different specimen source), the inspector must verify that the laboratory has established the accuracy, precision, analytical sensitivity, interferences, analytical specificity, and reportable range of the test procedure. If the system is FDA-cleared or approved and unmodified, the laboratory only has to verify these factors. There must be a calibration procedure and records 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 written 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 the responsible pathologist and signed by the pathologist. The final report must include a reference interval 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, and name and address of the laboratory where staining and image analysis were performed.

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 must 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 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 must be signed (either electronic or physical signature) by the diagnosing pathologist, and the laboratory must have a procedure that ensures and documents that the diagnosing pathologist has reviewed and approved the completed report before its release. The laboratory also must have a policy regarding the timely communication and documentation of significant or unexpected diagnostic findings.

**Autopsy Pathology:** The checklist emphasizes quality management components, such as timely reporting of both preliminary and final diagnostic findings, and incorporation of the autopsy findings into the institutional QM plan to enhance patient care. Laboratory policies and procedures must include provisions for safety issues to properly conduct autopsies on patients with known or suspected infectious diseases. The checklist section on the autopsy room contains requirements for proper conditions and for QC of the equipment used.

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:** This checklist section is concerned with QC issues such as 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.

**In Vivo Microscopy:** The In Vivo Microscopy (IVM) checklist section applies to technologies for clinical practice, in which a physician views digitized or analog video or still image(s) or other data, and renders an interpretation that is included in a formal diagnostic report or in the patient record. Examples of IVM technologists include confocal microscopy, optical coherence tomography, multiphoton microscopy, and optical spectroscopy and spectroscopic imaging. It can be used for the following applications:
• Intra-procedural guidance of biopsy or tissue excision
• Surgical (intraoperative) guidance
• Primary evaluation and/or diagnosis
• Screening
• Intra- or extra-institutional consultation
• Post-procedural evaluation and/or diagnosis

Informal reviews without formal reporting and educational or research-only use of these systems is not included as part of the CAP inspection process.

Inspectors will confirm that the IVM service has performed validation studies for the intended diagnostic purpose and has trained all users of the IMV system. Patient reports must be signed by the physician who interprets the IVM data sets and include the dataset source, the imaging technology, and any limitations of the result.
INSPECTING THE LABORATORY SECTIONS
CHEMISTRY AND TOXICOLOGY (CHM)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry and Toxicology</td>
<td>69</td>
</tr>
<tr>
<td>Calibration, Calibration Verification, &amp; Analytical Measurement Range</td>
<td>71</td>
</tr>
<tr>
<td>Maximum Dilution/Concentration</td>
<td>71</td>
</tr>
<tr>
<td>Waived Test Requirements</td>
<td>71</td>
</tr>
</tbody>
</table>

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 Applicable to All Laboratory Sections.

The Chemistry and Toxicology Checklist (CHM) addresses:

- Basic chemistry procedures, typically performed on automated and semi-automated instruments, including blood gas analysis and oximetry
- Toxicology testing, including 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 records of radiation exposure, and 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 recorded. 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.

5 10 CFR31.11
Laboratories performing only **blood gas testing** in a dedicated space (e.g., main laboratory, respiratory therapy) use the CHM Checklist, but will receive requirements related only to blood gas and oximetry testing, as applicable. Laboratories performing blood gas testing at or near the patient bedside (e.g., portable instruments) use the Point-of-Care Testing Checklist. Blood gas QC requirements include at least one level of control for pH, pCO₂, and pO₂ every eight hours of patient testing, with a low and high level required each day of patient testing. If an electronic/built-in internal control system is used in lieu of daily external control material samples, an individualized quality control plan following the requirements in the All Common Checklist must be implemented. 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 perform certain tests exclusively for **legal** purposes (e.g., alcohol for traffic law enforcement and criminal justice). In this case, the performance of legal testing must meet forensic, not clinical laboratory, standards. These forensic requirements include the 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.

The inspector must use the Chemistry 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 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 QC 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 (e.g., 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. Review must include records from across all test systems/instruments.

The Chemistry and Toxicology Checklist addresses laboratory equipment such as pipettes, glassware, analytical balances, spectrophotometers, and other basic analytic systems. Refer to Inspecting the Laboratory Sections - Requirements Applicable 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 must be thoroughly examined. When analytic systems are maintained for backup purposes and are infrequently
used, evaluation must be directed to system maintenance and the adequacy of correlation between analyzers.

Calibration, calibration verification, and analytical measurement range (AMR): Verification records must be examined closely to ensure that the analytic system stability meets the claims of the instrument/reagent manufacturer. Calibration must be performed according to manufacturer’s instructions. Calibration or calibration verification must be performed at least every six months, at changes of reagent lots for chemically or physically active or critical components, if QC materials reflect an unusual trend or shift, or after major preventive maintenance. If excessive time has elapsed between calibrations, a separate calibration verification process is required. AMR verification must be performed at a minimum of every six months, using 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 at least every six months.

Maximum Dilution/Concentration: For analytes that may have results falling outside the limits of the AMR, the inspector must confirm 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 at least every two years thereafter as part of the procedure manual review by the laboratory director or designee.

The laboratory must have written procedures for all required maintenance, with frequency and schedule noted. There must be records of all required maintenance. These records must be reviewed and assessed at least monthly by the laboratory director or designee.

Waived Test Requirements: Certain checklist requirements are different for waived tests and nonwaived tests. Refer to the Inspecting the Laboratory Sections – Requirements Applicable to All Laboratory Sections - Waived Test Requirements section of this manual for specific details.
INSPECTING THE LABORATORY SECTIONS
CLINICAL BIOCHEMICAL GENETICS (CBG)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist Usage</td>
<td>72</td>
</tr>
<tr>
<td>Inspector Requirements</td>
<td>72</td>
</tr>
<tr>
<td>Preparing to Inspect</td>
<td>73</td>
</tr>
<tr>
<td>Specimen Collection and Handling</td>
<td>73</td>
</tr>
<tr>
<td>Calibration and Standards</td>
<td>73</td>
</tr>
<tr>
<td>Controls</td>
<td>73</td>
</tr>
<tr>
<td>Method and Instrument Systems</td>
<td>73</td>
</tr>
<tr>
<td>Equipment Maintenance</td>
<td>73</td>
</tr>
<tr>
<td>Laboratory Safety</td>
<td>74</td>
</tr>
</tbody>
</table>

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 Applicable to all Laboratory Sections.

Checklist Usage: The Biochemical Genetics Checklist is required for inspection of laboratories performing biochemical genetics testing. It 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 require 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.

Inspector Requirements: Inspection of a biochemical genetics laboratory requires special knowledge of IEMs and the laboratory procedures used for their diagnosis. The inspector must have working knowledge of high performance liquid chromatography (HPLC) and/or automated amino acid analyzer, gas chromatography/mass spectrometry (GC/MS), tandem mass spectrometry, and enzymatic methods for the diagnosis of IEMs. He/she must 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 must 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 testing instruments are near one another. The inspector must ensure that there are specific instructions for the proper collection, handling, transport, and submission of newborn screening blood spots.

Calibration and Standards: The laboratory must examine verification records closely to ensure that the analytical system stability meets the claims of the instrument/reagent manufacturer. Calibration must be performed according to manufacturer instructions. Calibration or calibration verification must be performed at least every six months. If excessive time has elapsed between calibrations, a separate calibration verification process is required. Analytical measurement range verification (AMR) 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 at least every six months.

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, and are periodically processed like a patient/client sample to monitor the ongoing performance of the entire analytic process. The laboratory must be able to demonstrate ongoing system accuracy and stability. Appropriate multilevel control specimens must be used at least daily on days when patient specimens are tested.

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 must be properly operated, maintained, serviced, and monitored to ensure that malfunctions of these instruments and equipment do not adversely affect the analytical results.
The laboratory must have written procedures for all required maintenance, with frequency and schedule noted, that are as thorough and as frequent as specified by the manufacturer.
must be evidence and records of all required maintenance. The instrument and equipment maintenance records must be reviewed and assessed at least monthly by the laboratory director or designee.

**Laboratory Safety:** The inspector must, 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.
INSPECTING THE LABORATORY SECTIONS
CYTOGENETICS (CYG)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspector Requirements</td>
<td>75</td>
</tr>
<tr>
<td>Inspection Process</td>
<td>75</td>
</tr>
<tr>
<td>Procedures and Test Systems</td>
<td>76</td>
</tr>
<tr>
<td>Cells Counted and Analyzed</td>
<td>76</td>
</tr>
<tr>
<td>Band Resolution</td>
<td>76</td>
</tr>
<tr>
<td>In Situ Hybridization (ISH)</td>
<td>76</td>
</tr>
<tr>
<td>HER2</td>
<td>76</td>
</tr>
<tr>
<td>Genomic Copy Number Assessment – Microarray</td>
<td>76</td>
</tr>
<tr>
<td>Reports</td>
<td>76</td>
</tr>
</tbody>
</table>

*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 Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Applicable to All Laboratory Sections.*

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 non-neoplastic tissues. The laboratory may use conventional, in situ hybridization (ISH), and microarray techniques.

**Inspector Requirements:** Cytogenetics inspectors must 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 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 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. The inspector will review the records of failed cultures and suboptimal analyses and look for evidence that the reasons for culture failures have been investigated and actions taken when improvement opportunities occur. For prenatal testing, there must be an attempt to communicate additional testing options for follow-up on abnormal results.

**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 must 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 must be exceptional and explainable.

**ISH:** Review a sampling of ISH cases and controls, evaluation signal, background, and morphology. There must be policies, procedures and records of validation of all ISH probes. If ISH 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 federal regulations.

**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 and may be periodically revised.

**Genomic Copy Number Assessment—Microarray:** Review validation data for implementation of new methods and ongoing records of continual quality monitoring of assay performance.

**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, ordering physician name, specimen source, date of specimen receipt, date of report, clinical indication for the test, number of 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.
• The inspector will:
  o Review several normal and abnormal cases and investigate how the laboratory handles a sample received without clinical information or diagnosis.
  o Examine photographs and other records to ensure that they substantiate the final interpretation of each case.
  o Investigate how abnormal results are communicated to referring physicians.
  o Ensure that the most current edition of the *International System for Human Cytogenetic Nomenclature (ISCN)* is used correctly in the final report for conventional cytogenetics.
  o Confirm that ISH result interpretations are made with reference to an internal and/or external control for each ISH analysis.
- Verify that any errors occurring in the final report (such as typographical sex-designation errors) are thoroughly investigated and the results of the investigation recorded.
- Ensure that preliminary reports, especially verbal or telephone reports, are recorded on the final report.
- The final report contains recommendations for genetic counseling or additional studies, when indicated.
- Report turnaround times: 90% of reports must be available as follows (the term “days” means calendar days):

<table>
<thead>
<tr>
<th>Test</th>
<th>Turnaround Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amniotic fluid and chorionic villi analyses</td>
<td>Final: 14 days</td>
</tr>
<tr>
<td>Nonneoplastic blood</td>
<td>Final: 28 days</td>
</tr>
<tr>
<td>Stat chromosomal analysis</td>
<td>Preliminary: 3 days</td>
</tr>
<tr>
<td>Stat chromosomal analysis</td>
<td>Final: 7 days</td>
</tr>
<tr>
<td>Nonneoplastic, fibroblast</td>
<td>Final: 6 weeks</td>
</tr>
<tr>
<td>Neoplastic blood and bone marrow</td>
<td>Final: 21 days</td>
</tr>
</tbody>
</table>
INSPECTING THE LABORATORY SECTIONS
CYTOPATHOLOGY (CYP)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel and Screening</td>
<td>78</td>
</tr>
<tr>
<td>Reports</td>
<td>79</td>
</tr>
<tr>
<td>On-site Case Review</td>
<td>80</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>81</td>
</tr>
<tr>
<td>Safety</td>
<td>81</td>
</tr>
<tr>
<td>Quality Management</td>
<td>82</td>
</tr>
</tbody>
</table>

*Inspection of cytopathology is not limited to the contents of the Cytopathology Checklist, but includes all applicable portions of 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 Applicable to all Laboratory Sections.*

The inspector must 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 must plan to spend several hours inspecting the cytopathology section regardless of the case volume. The on-site inspection will require review of slides and reports, 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 laboratory must also be able to produce any slide upon the request of an inspector during the required five-year retention period for gynecologic and nongynecologic slides and 10 years for fine-needle aspiration slides.

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 records that affirm performance of their respective responsibilities as outlined in the checklist. The
cytopathologist may serve as the general supervisor. Alternatively, a qualified cytotechnologist with at least three years of full-time experience within the preceding 10 years may also 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 of 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 must evaluate whether the facility provides adequate space and a suitable environment for screening, together with applicable QC and quality management data, when judging the adequacy of cytopathology laboratory staffing. Although CLIA establishes 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 must review the written 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 recorded 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 (CYP.08550). Laboratories must ensure that CLIA requirements are fulfilled in addition to following workload calculations as defined in the July 27, 2010 FDA Alert: How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-automated Gynecologic Cytology Screening Devices. This FDA alert provides the following calculation method, which applies to semi-automated cytology screening systems currently on the market:

- 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 must be used to count workload, not exceeding the CLIA maximum limit of 100 slides equivalents in an eight-hour day.

If state or local regulations for workload recording are more stringent, they must be followed.

**Reports:** Written 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 they do not reflect current understanding of neoplasia, has no comparable equivalent in diagnostic histopathology terminology, and does not provide for diagnosis of non-neoplastic conditions.

The laboratory must have a written 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 cytology specimens (ie, urine, fluids, washings and brushings). When appropriate (particularly for fine-needle aspiration samples of mass lesions), the laboratory must 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 must be identifiable by name, initials, or another 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 record 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 written 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 performed 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. Signed copies of Cytopathology reports may be retained in either paper or electronic format. Images of signed 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 decide 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 have been offered by members of the CAP Cytopathology Resource Committee and endorsed by the Commission on Laboratory Accreditation:

Cases are to be selected from a variety of diagnostic categories. Time must be allotted to review at least 10–15 cases. It is strongly recommended that the Inspector 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 must be evaluated for technical quality and specimen adequacy.
2. Significant cells must have been identified.
3. Slides must 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 must 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) are not to 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 verify and record 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 verification and instrument monitoring recommendations, the laboratory must record the specific verification procedure used.

The laboratory must record the appropriate technical and interpretive training for each instrument used. Instrument performance must be routinely verified and monitored, with corrective actions recorded and procedures for handling cases during instrument failure. Ongoing monitoring of instrument function and maintenance on all devices must be recorded. Monitoring of device operation must be in accordance with manufacturers' instructions. If the manufacturer does not provide monitoring recommendations, the laboratory must record 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, must 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 must 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 (QM):** The facility's QM program must address the validation of both normal and abnormal diagnoses and the assessment of laboratory and personnel performance. Quality measures for abnormal findings must include such activities as peer and hierarchical review, correlation of cytologic findings with histologic and clinical findings, recorded 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.

For US laboratories and other laboratories subject to CLIA, 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 rescreening program must include negative gynecological smears received within five years of a new high-grade intraepithelial lesion or cancer diagnosis, if applicable. Slides screened by pathologists are exempt from this requirement.

Laboratories not subject to US regulations may follow the US requirement for rescreening or may use an alternative procedure. Alternative procedures for 10% rescreening may include, but are not limited to a rapid rescreening of all cases or rapid prescreening of all cases with targeted rescreening of discrepant cases. Slides must be rescreened or prescreened in their entirety, including slides processed by imaging instruments that select a limited number of microscopic fields for examination.

The inspector must assess the procedures for rescreening and hierarchical 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 must be reviewed; benchmark data from CAP interlaboratory comparison programs are useful in evaluating the laboratory’s statistical results.

All quality surveillance activities must be recorded, 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, 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.
INSPECTING THE LABORATORY SECTIONS
FLOW CYTOMETRY (FLO)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspector Qualifications</td>
<td>84</td>
</tr>
</tbody>
</table>

*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 Applicable 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 inspector database specialist at 800-323-4040 ext. 7380, for the names of additional qualified inspectors.

This checklist includes requirements on 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 have written procedures and records for monitoring the optical alignment and instrument reproducibility at least daily (or after each time the flow cytometer is restarted). Appropriate fluorochrome standards, (eg, fluorescent beads) must be run each day that the instrument is used as part of the calibration, with the results recorded for QC purposes. 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 must consist of external positive controls for lymphocyte subsets, CD34 stem cell enumeration, and leukemia/lymphoma samples. In some leukemia/lymphoma situations, the residual normal cells in the patient’s sample can be used as the control. Like the external controls, there must be written guidelines defining objective criteria for acceptable performance of the normal cell populations and written records of the evaluation of the actual periodic performance.

When antigen-positive controls are not readily available through commercial controls or patient materials, the laboratory director must implement an equivalent procedure to meet the positive control requirements (ie, CD1a, CD103, etc.). This may include cryopreserved or fresh cell lines, patient material, or antigen validated material. At a minimum, there must be testing of rare antigens performed at least semiannually.

For laboratories performing only the interpretation component of flow leukemia/lymphoma immunophenotyping data (ie, the flow technical component is performed at an outside flow
laboratory), the following Flow Cytometry Checklist requirements apply: FLO.18385, FLO.23675, FLO.23706, FLO.30605, FLO.30640, FLO.30730, and FLO.30790. Additionally, requirements located in the All Common Checklist addressing proficiency testing, quality management, procedure manual, specimen rejection, and results reporting are applicable.
INSPECTING THE LABORATORY SECTIONS
HEMATOLOGY AND COAGULATION (HEM)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automated Blood Cell Counting</td>
<td>86</td>
</tr>
<tr>
<td>Automated Differential Counters</td>
<td>87</td>
</tr>
<tr>
<td>Manual Blood Films</td>
<td>87</td>
</tr>
<tr>
<td>Automated Reticulocytes</td>
<td>87</td>
</tr>
<tr>
<td>Manual Reticulocytes</td>
<td>87</td>
</tr>
<tr>
<td>Bone Marrow Preparations</td>
<td>88</td>
</tr>
<tr>
<td>Abnormal Hemoglobin Detection</td>
<td>88</td>
</tr>
<tr>
<td>Body Fluids</td>
<td>88</td>
</tr>
<tr>
<td>Semen Analysis</td>
<td>88</td>
</tr>
<tr>
<td>Coagulation Tests</td>
<td>88</td>
</tr>
<tr>
<td>Calibration, calibration verification, and analytical measurement range</td>
<td>89</td>
</tr>
<tr>
<td>Waived Test Requirements</td>
<td>89</td>
</tr>
</tbody>
</table>

*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 Applicable to All Laboratory Sections.*

**Automated Blood Cell Counting**: The laboratory must have a written procedure for calibration of automated complete blood count (CBC) instruments, including criteria for 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 QC 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 (normal and high) are required for each 24 hours of patient testing. 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 must 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 must 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. QC 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 QC material must 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 that have clinically important results flagged by the automated counter.

**Manual Blood Films:** There must be written 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 annually include:

- Circulation of blood films with defined leukocyte differential distributions and specific qualitative abnormalities of each class of cells
- Multiheaded microscopy
- Use of blood or bone marrow photomicrographs with referee and consensus identifications, such as those from previous CAP Surveys
- Use of 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. Written criteria must be defined 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 FDA-approved commercial kits, 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.
**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 a further confirmatory testing.

**Body Fluids:** The procedure manual must address handling of partially clotted specimens, cell clumps and debris noted during hemocytometry or automated counting. For instrument counts, the laboratory must have records of accuracy, precision, and upper and lower limits beyond which instrument counts are not reliable. Differentials must 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 annually 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 sperm morphology classification. Additional requirements for sperm preparation for therapeutic procedures 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 offer tests for defining or monitoring disseminated intravascular coagulation if applicable to the patient population served.

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

The laboratory must report patient results with the accompanying reference intervals. 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 records to demonstrate 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 geometric 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.

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. Pooled plasma prepared in the laboratory or commercial products comprised of at least 20 apparently healthy donors 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 must examine sample assay data to determine if appropriate calibration points and two dilutions of patient plasma are routinely used.

The following applies to hemostasis test methods that are calibrated and directly measure the concentration or activity of an analyte by employing enzyme immunoassay (EIA), immunoturbidity or chromogenic methods:

NOTE: It does not apply to clot-based methods including PT, aPTT, thrombin time, factor assays and fibrinogen, lupus anticoagulant, activated protein C resistance, qualitative and semi-quantitative assays) or any platelet function assays, including ristocetin cofactor activity.

Calibration, calibration verification, and analytical measurement range (AMR): Verification records must be examined closely to ensure that the analytical system stability meets the claims of the instrument/reagent manufacturer. Calibration verification must occur at the frequency required by the manufacturer, but no less than every six months and whenever the following occur:

1. At complete changes of reagents (ie, change in type of reagent from same vendor, or change to a different vendor)
2. If QC materials reflect an unusual trend or shift or are outside of the laboratory’s acceptable limit, or other means of assessing and correcting unacceptable control values fail to identify and correct the problem
3. After major maintenance or service
4. When recommended by the manufacturer
5. At least every six months

AMR verification must be performed at least 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.

Waived Test Requirements: Certain checklist requirements are different for waived tests and nonwaived tests. See the Inspecting the Laboratory Sections - Requirements Applicable to All Laboratory Sections - Waived Test Requirements section of this manual for more information.
Inspecting the Laboratory Sections
HISTOCOMPATIBILITY (HSC)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspector Qualifications</td>
<td>90</td>
</tr>
<tr>
<td>Before the Inspection</td>
<td>91</td>
</tr>
<tr>
<td>During the Inspection</td>
<td>91</td>
</tr>
<tr>
<td>Quality Control and Proficiency Testing</td>
<td>91</td>
</tr>
<tr>
<td>Leadership</td>
<td>91</td>
</tr>
<tr>
<td>Reports</td>
<td>91</td>
</tr>
<tr>
<td>Personnel</td>
<td>91</td>
</tr>
<tr>
<td>Inspection Resources</td>
<td>92</td>
</tr>
</tbody>
</table>

**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 Applicable 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 must have the qualifications for Section Director (Technical Supervisors) of a CAP-accredited histocompatibility laboratory or have experience in a supervisory position and at least two years of experience in clinical histocompatibility. The inspector must 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
- Nontransplantation clinical purposes (platelet transfusion, disease risk assessment, etc)
- Relationship testing
Technical

• Serologic typing, crossmatching, and antibody identification
• Flow cytometry, crossmatching, and antibody determination
• Other solid phase antibody identification methods (ELISA, Microarrays)
• DNA typing (eg, SSP, SSOP)
• DNA sequence-based typing
• STR systems for chimerism analysis post-allogeneic HPC transplantation

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 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 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 must 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 must 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.

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 (QC) and Proficiency Testing (PT): The inspector must review required PT or alternative performance assessment results and QC for all tests performed in detail with emphasis on records of corrective action. It is important that the inspector verify that the laboratory participates in proficiency testing programs accepted by the CAP’s Commission on Laboratory Accreditation.

Leadership: Policies and procedures must 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 must evaluate the degree of involvement of the supervisor and director.

Reports: Reports vary considerably among histocompatibility laboratories, and the inspector must 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
records of sufficient continuing education credits for section directors, supervisors, and other
technical personnel. The technical supervisor (section director) must have a MD, DO, or PhD in
chemical, physical, biological, or clinical laboratory science, and either four years training and
experience in histocompatibility, or two years of 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.
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 Applicable to All Laboratory Sections.

For qualitative tests, the laboratory must perform positive and negative controls at least once each day of analysis. 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 an internal QC process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily QC requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director to address the use of the alternative control system. At a minimum, manufacturers’ instructions must be followed. For panels or batteries, controls must be employed for each analyte sought in patient specimens.
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 Applicable 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 referral laboratory when necessary for patient management.

Quality Control (QC): This section includes QC requirements for prepared and purchased culture media, staining procedures, reagents, antimicrobial susceptibility tests, waived tests, specimen collection, specimen handling, instruments, and equipment. For each procedure, medium, reagent, and item of equipment to be monitored, the laboratory must define control methods, as well as the frequency of testing, limits for acceptability, and action to be taken when not acceptable.
Media: The inspector must review policies, procedures, and records relating to the following for culture media. All media used, whether purchased or prepared in-house by the laboratory, are sterile, able to support growth, and as appropriate, select or inhibit specific organisms, 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 records that each lot is tested for sterility, ability to support growth or show selectivity for appropriate organisms, and exhibit the intended biochemical reactivity at the time of receipt or concurrent with use in the laboratory. An individualized quality control plan (IQCP), including all elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the QC performed by the media supplier for media listed as “exempt” in the CLSI/NCCLS Standard M22-A3, Quality Control 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. If an IQCP is in place, the end user laboratory may record this information in place of the more detailed documentation of media performance for affected media.
- The end user must record that each shipment has been visually examined upon receipt for breakage, contamination, appearance, and 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 sterility, ability to support growth, selective properties, and appropriate biochemical reactions using QC methods employed for media manufactured in-house.
- QC organisms such as ATCC strains, well-characterized laboratory strains, or strains recommended by the manufacturer are used to check stains, reagents, and susceptibility test methods. These organisms must be maintained in a manner to preserve their bioreactivity, phenotypic characteristics, and integrity.
- The director is responsible for the quality and performance of media. All media failures and the resultant corrective action taken must be recorded.

Identification Systems: The laboratory must test each shipment and lot of an identification system (a system using two or more substrates or two or more reagents) for appropriate performance. A laboratory may perform streamlined QC as defined in CLSI M-50 and following manufacturer’s instructions, only if it implements an individualized quality control plan (IQCP). Without an IQCP, the CAP/CLIA default QC is to test each substrate in an identification system for positive and negative reactivity using appropriate organisms.

Susceptibility Testing: 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 if an
IQCP is implemented which justifies this practice. The CLSI Standards recommend two methods of verification for the reduction of QC 1) performance of a study with records of satisfactory 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) or 2) records of a study with three separate inoculum suspensions for five consecutive testing days with no more than one of fifteen values outside the accepted QC range. 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 recorded. Before returning to a weekly QC frequency, the laboratory must record five consecutive days of satisfactory QC results.

**Stains:** Quality control (QC) for stains must be documented as follows:
- **Gram stain:** QC must be performed with each new batch and lot of stains, and at least weekly against gram positive and gram negative organisms.
- **Non-immunofluorescent stain (other than Gram stains):** QC must be performed with positive and negative QC organisms each day of use, and for each new batch, lot number, and shipment.
- **Fluorescent Stains:** QC must be performed with positive and negative QC organisms 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, and this must be assessed at least annually.

**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 (routine and supplemental) 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 must 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 cultures.

**Waived Test Requirements:** Certain checklist requirements are different for waived tests and nonwaived tests. See the Requirements Applicable to All Laboratory Sections; Waived Test Requirements area of this accreditation manual for specific detail.

**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 QC, smears, processing, culture media, identification, and susceptibility testing of mycobacteria are contained in the checklist. The laboratory or referral
laboratory must use fluorochrome stains for microscopic examination of slides prepared from primary patient specimens (unless local regulations require a different stain).

**Mycology:** For stains such as Gomori methenamine silver and Giemsa, the slide itself serves as the negative control. Controls for KOH preparations are not required. QC for susceptibility testing in mycology must be performed each day of testing using appropriate organisms unless an IQCP is implemented which justifies less frequent QC (no less than weekly).

**Parasitology:** The laboratory must perform concentration procedures and permanent stained preparations on all stools submitted for parasitological microscopic examination. Laboratories must have an ocular micrometer available for determining the size of eggs, larvae, cysts, trophozoites, and microfilaria or other blood borne parasites. 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 must ensure that the laboratory has fulfilled requirements for formaldehyde testing.

**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 re-feeding does not require additional testing for sterility. Incubation time of cultures must be adequate to recover viruses for indicated services offered.

**Molecular Microbiology:** This section is used to inspect laboratories that perform molecular testing for infectious diseases. The one exception to this is for next generation sequencing (NGS): If a laboratory is using NGS methods for infectious disease testing, the applicable NGS checklist requirements found in the Molecular Pathology Checklist must be used in addition to the Microbiology checklist. The Molecular Microbiology section includes subsections for general requirements, FDA-cleared/approved non-amplification methods, FDA-cleared/approved amplification methods, modified FDA-cleared/approved methods, and laboratory-developed tests (LDTs).

The inspector of molecular microbiology should actively practice in this area, but the individual need not be on the CAP list of molecular pathology inspectors unless NGS testing is being performed, in which case a NGS specialty inspector must be used.

Many of the infectious disease molecular tests are multiplex tests. A multiplex test simultaneously detects a defined set of analytes (eg, two or more pathogen-specific nucleic acid sequences) from a single run or cycle of the assay. When checking each new lot and shipment of multiplex tests, at least two analytes must be individually verified. Although a sample of analytes may be used to verify each lot and shipment, the analytes verified must be rotated.
periodically as defined in laboratory procedure to assess all analytes in the multiplex test over time.
INSPECTING THE LABORATORY SECTIONS
MOLECULAR PATHOLOGY (MOL)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist Usage</td>
<td>99</td>
</tr>
<tr>
<td>Inspector Requirements</td>
<td>99</td>
</tr>
<tr>
<td>Preparing to Inspect</td>
<td>99</td>
</tr>
<tr>
<td>Assay Verification &amp; Validation</td>
<td>100</td>
</tr>
<tr>
<td>Next Generation Sequencing (NGS)</td>
<td>100</td>
</tr>
<tr>
<td>In Situ Hybridization (ISH)</td>
<td>100</td>
</tr>
<tr>
<td>Result Reporting</td>
<td>100</td>
</tr>
<tr>
<td>Quality Management</td>
<td>101</td>
</tr>
</tbody>
</table>

*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 Applicable to All Laboratory Sections.*

**Checklist Usage:** The Molecular Pathology Checklist is used for the inspection of laboratories performing clinical molecular testing, including, but not limited to, applications related to oncology, hematology, inherited disease, pharmacogenetics, noninvasive prenatal testing, HLA typing, forensics, and parentage. The Microbiology Checklist must be used to inspect laboratories that perform molecular testing for infectious disease applications.

**Inspector Requirements:** Molecular pathology inspectors must 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 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, the Laboratory General Checklist and the All Common Checklist, and must review the checklists prior to the inspection. 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 verify familiarity with the type and scope of testing the laboratory is performing.
**Assay Verification and Validation:** The inspector will ensure that, prior to clinical implementation of a new assay, the laboratory has verified or established the appropriate method performance characteristics.

For FDA-cleared or approved tests, the inspector will use the Method Performance Specifications section of the All Common Checklist to ensure that the laboratory has recorded its verification of the following method performance characteristics: accuracy, precision, reference range, and reportable range.

For modified FDA-cleared or approved tests and laboratory-developed tests (LDTs), the inspector will use the Assay Validation section of the Molecular Pathology Checklist, along with the All Common Checklist, to ensure that the laboratory has established the following method performance characteristics: accuracy, precision, reference range, reportable range, analytical sensitivity, analytical specificity, and any other performance characteristics (e.g., specimen stability, reagent stability, linearity, carryover, cross-contamination). Validations must be performed with samples for each type of specimen expected for the assay (blood, fresh/frozen tissue, paraffin embedded tissue, prenatal specimens, etc.). In addition, the clinical performance characteristics of each assay must be evaluated. Prior to reporting patient results, the laboratory director (or designee who meets CAP director qualifications) must sign a summary statement for the review of the validation studies and approval of the test for clinical use.

**Next Generation Sequencing (NGS):** NGS-based assays include, but are not limited to (1) multigene panels for a variety of inherited disorders and oncology conditions; (2) human leukocyte antigen locus characterization; (3) noninvasive prenatal testing (4) exome sequencing for candidate gene discovery in inherited disorders and characterization of the mutational landscape in tumors; and (5) whole genome sequencing.

The NGS specialty inspector must be familiar with NGS testing and how it incorporates three processes: (1) an analytical wet bench process, including specimen handling, library preparation, and sequence generation; (2) an analytical bioinformatics process, including sequence alignment or assembly, variant calling, variant annotation, and variant prioritization and/or interpretation performed with the aid of algorithms and software; and (3) the final interpretation and reporting of NGS results. These three processes are inextricably linked, and their combination is needed to achieve optimization and validation of the total NGS testing process. For NGS, the inspector must assess the validation, QC, quality metric monitoring, implementation of new technology and software releases, and how the laboratory documents and stores the large volume of data produced by NGS.

**In Situ Hybridization (ISH):** The inspector must be aware that the inspection checklist contains requirements from the ASCO/CAP guidelines for HER2 (ERBB2) relating to validation of HER2 (ERBB2) 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.

**Result Reporting:** The inspector will verify that the final report is reviewed and signed by the section director (or a qualified designee who meets section director qualifications) 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 must verify that reports for LDTs contain a statement that the assay was developed by the laboratory. Laboratories subject to US regulations often include an LDT disclaimer as follows: “This test was developed and its performance characteristics determined by < insert laboratory/company name>. It has not been cleared or approved by the FDA. The laboratory is certified under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.” The report should also contain a brief description of the method and any performance characteristics needed for clinical use unless the information is readily available to the clinician in an equivalent form (e.g., in a test catalog).

**Quality Management (QM):** The inspector must ensure that the laboratory investigates its failed runs and suboptimal analyses, and uses these for improvement opportunities. The inspector must also verify that the laboratory is maintaining test result statistics to detect trends. In addition, the inspector must confirm that turnaround times are being monitored, especially for clinical situations in which rapid completion is essential.

For NGS, the inspector must ensure that the QM program specifies the quality metrics and QC parameters that are used to assess wet bench process performance. Metrics and parameters will vary between technology platforms and tests typically include, but are not limited to: NGS library fragment size distribution, NGS cluster densities, and NGS instrument sequence output, base quality and error rates. For the bioinformatics process, the following quality metrics and QC parameters should be assessed (all are compared to a reference average that is determined during assay validation): total reads generated for each sample, percent of unique reads aligned to target, average coverage of targeted bases, and percent of bases covered at specific read depths. In addition, the inspector should ensure that the laboratory assesses the test reproducibility over time, and for somatic cancer assays, that the laboratory monitors the limit of detection controls for determination of assay sensitivity over time.
**INSPECTING THE LABORATORY SECTIONS**

**POINT-OF-CARE (POC) TESTING**

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition and Applicability of Point-of-Care Testing</td>
<td>102</td>
</tr>
<tr>
<td>Waived Testing Requirements</td>
<td>102</td>
</tr>
<tr>
<td>Inspecting Point-of-Care Testing</td>
<td>103</td>
</tr>
<tr>
<td>Personnel</td>
<td>103</td>
</tr>
<tr>
<td>Provider-Performed Testing</td>
<td>104</td>
</tr>
</tbody>
</table>

*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 Applicable to All Laboratory Sections.*

**Definition and Applicability of Point-of-Care Testing:** 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 (eg, capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (eg, 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. The POC checklist covers only tests that are classified as waived or moderately complex (provider-performed microscopy [PPM] is a subset of moderately complex tests). It may also be used to inspect FDA-cleared/approved point-of-care tests that are modified by the laboratory. Modified FDA-cleared/approved tests are subject to the nonwaived checklist requirements and high complexity personnel qualifications. 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 different for waived tests and nonwaived tests. However, checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, and safety are the same for both waived and nonwaived tests. Refer to the Inspecting the Laboratory Sections - Requirements Applicable to All Laboratory Sections section – Waived Test Requirements section of this manual for more information.
Inspecting Point-of-Care Testing: Tests- and 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, a discipline-specific checklist (eg, hematology, microbiology) may be required. Blood gas testing - performed at the point of care or near patient treatment areas may be inspected with the POC Checklist.

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 (under one CLIA number) 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.

POCT programs are frequently centrally coordinated with designated qualified personnel who review testing procedures and QC and who conduct training of the testing personnel. When records are maintained centrally by a designated coordinator or POCT director, only one copy of the Point-of-Care Testing Checklist is used for inspection. All test sites under the coordinator are included as one section unit. The inspector will review all centrally maintained records and visit a sampling of the testing sites in order to evaluate compliance with the standards. 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.

Personnel: Each person performing POCT must maintain satisfactory levels of competence. There must be records for the completion of training before the person performs patient testing. Requirements for competency assessment vary depending on the complexity of testing performed.

- For nonwaived testing, competency must be assessed at least twice during the first year of an individual's duties. After an individual has performed his/her duties for one year, competency must be assessed annually. The Personnel section of the POC Checklist requires assessment of six elements of competency as applicable to an individual's.

- For waived testing, competency must be assessed at least annually. It is not necessary to assess all six elements at each assessment event. The POCT program may select which elements to assess. If more stringent state or local regulations are in place for competency assessment of waived testing, they must be followed.

- For provider-performed testing (PPT), competency of physicians and midlevel practitioners performing provider-performed microscopy procedures (moderate-
complexity testing) must be assessed following the requirements for nonwaived testing. If waived testing is performed, competency of the physicians and providers is assessed following requirements for waived testing.

All point-of-care testers who are performing nonwaived testing must be included on the Laboratory Personnel Evaluation 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, licenses, or primary source verification reports to confirm that the personnel are qualified to perform testing per CLIA requirements. **NOTE: State issued personnel licenses for nurses, respiratory therapists, and radiology may not be used to demonstrate educational qualifications to perform nonwaived testing. Only laboratory personnel licensure from states that require laboratory personnel licensure may be used in lieu of a diploma or transcript.**

**Provider-Performed Testing:** The CAP defines provider-performed testing (PPT) as testing that is personally performed by a physician or midlevel practitioner (a physician assistant, nurse practitioner, certified nurse midwife, etc) 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 and All Common Checklist do **not** apply to PPT.

This section is not applicable if PPT is performed under a different CLIA number than the laboratory. The PPT category is **not** the same as the US CLIA term “provider-performed microscopy” (PPM). Rather, PPT includes a combination of waived tests and PPM. PPT is currently limited to the following tests:

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

* If nonwaived methods are used for these tests, other sections of the Point-of-Care Testing Checklist and the All Common Checklist are required.
The current list of tests waived under CLIA may be found at:

*The performance of tests, other than those tests listed above, are subject to inspection with the other sections of the Point-of-Care Testing and All Common Checklists and/or other discipline-specific checklists, as appropriate.*
INSPECTING THE LABORATORY SECTIONS
TEAM LEADER ASSESSMENT OF DIRECTOR & QUALITY CHECKLIST

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist Usage</td>
<td>106</td>
</tr>
<tr>
<td>Inspection Process</td>
<td>106</td>
</tr>
<tr>
<td>Laboratory Director Qualifications and Responsibilities</td>
<td>107</td>
</tr>
</tbody>
</table>

NOTE: The Team Leader Assessment of Director & Quality Checklist (TLC) does not apply to the Biorepository Accreditation Program.

**Checklist Usage:** This checklist is used to evaluate the qualifications of the laboratory director and the effectiveness of the director in implementing the Standards of the Laboratory Accreditation Program, including the laboratory’s quality management plan. It is used to identify major or systemic deficiencies that reflect lack of director oversight in areas, such as QC, quality management, proficiency testing, employee qualifications and records, competency and training, and the maintenance of a safe work environment.

**Inspection Process:** 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 supervisory personnel and other 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 for appropriate director involvement
5. Interview with the hospital administrator (or an executive if the laboratory is an independent organization)
6. Interview with the chief of the medical staff or designated medical staff leader (for laboratories associated with a medical staff)
7. Discussion of deficiencies with team members. Deficiencies that directly affect patient safety, or are pervasive in the laboratory, may warrant a deficiency in the Director Oversight Responsibilities section of the checklist.

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. Discussion of the laboratory’s financial and/or contractual arrangements is prohibited. If for any reason the interviews are not performed, discuss the circumstances in the Inspector’s Summation Report.

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. Open-ended questions are usually best. For instance, “Tell me about how the annual quality management plan is put together?” will yield a much more revealing response than, “Do you review the quality management plan each year?” If the inspection reveals systemic problems, appropriate deficiencies from the Team Leader Checklist must be cited and elaborated upon in the Inspector’s Summary Report, Part A. The interview with the director is also an opportunity to review problem areas (eg, space, staffing) that the inspection might serve to resolve.

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, including timeliness and quality, and should determine the contribution of the laboratory director (and other pathologists) to the institution’s committees, quality management, patient safety and educational activities. Questions about improvements in laboratory service may be helpful.

**Laboratory Director Qualifications and Responsibilities:** The qualifications and responsibilities of the laboratory director are described in the Team Leader Checklist. The laboratory director must:

- Meet the qualifications found in the *Standards for Laboratory Accreditation*.
- Be a board-certified pathologist or other qualified physician or doctoral scientist, or possess commensurate qualifications.
- Have sufficient authority to implement the *Standards for Laboratory Accreditation*.

The director need not personally perform all functions described in the laboratory director responsibilities. Administrative functions may be delegated to qualified laboratory managers or supervisors. Medical and technical functions may be delegated to other physicians and qualified laboratory personnel. If some functions are delegated to others, there must be a written policy or other statement signed by the laboratory director authorizing them to perform tasks on behalf of the laboratory director. The laboratory director remains responsible to ensure that all personnel performing delegated functions are qualified to do so, and that the delegated functions are properly carried out. There are some functions that may not be delegated, such as provision of appropriately trained supervisory and technical staff and the identification of their responsibilities. The laboratory director must also record personal, on-site assessment of physical and environmental conditions and the adequacy of staffing.

If the laboratory director is not qualified to direct any of the individual sections of the laboratory, those sections must be directed by an appropriately qualified individual. The Laboratory General
Checklist contains requirements for section directors (technical supervisors), technical consultants, and clinical consultants.
**INSPECTING THE LABORATORY SECTIONS**

**TRANSFUSION MEDICINE (TRM)**

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Accession and Disposition Records</td>
<td>109</td>
</tr>
<tr>
<td>Technical Procedures</td>
<td>109</td>
</tr>
<tr>
<td>Blood and Blood Components</td>
<td>109</td>
</tr>
<tr>
<td>Storage and Issue of Tissues</td>
<td>110</td>
</tr>
<tr>
<td>Transfusion Related Activities</td>
<td>110</td>
</tr>
<tr>
<td>Donor Procedures and Apheresis</td>
<td>110</td>
</tr>
<tr>
<td>Hematopoietic Progenitor Cells</td>
<td>110</td>
</tr>
<tr>
<td>AABB Coordinated Inspections</td>
<td>110</td>
</tr>
</tbody>
</table>

*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 Applicable to All Laboratory Sections.*

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

**Component Accession and Disposition Records:** Component records must include records of each component or tissue from receipt/collection through processing, storage, testing, and final disposition, including transfusion records. The identity of each person performing any portion of testing or manufacturing must be recorded and retained per the record retention requirements in the Transfusion Medicine Checklist.

**Technical Procedures:** Blood typing and compatibility procedures will be directly observed by the inspector to verify that actual practice corresponds to the procedure manual, including the recording of results at the time of testing. The laboratory must validate or verify the acceptability of new test systems, equipment, and reagents prior to use. The inspector will 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 must be reviewed to ensure proper product labeling with all FDA-required information, correct assignment of expiration dates, maintenance of the sterility of the components, and appropriate QC. The inspector will 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, will 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).

**Storage and Issue of Tissues:** The laboratory must 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 for appropriate storage conditions, as well as disposition.

**Transfusion Related Activities:** The inspector will observe blood component administration procedures with particular emphasis on patient identification. Samples collected for compatibility testing and potential transfusion related requests must be positively and completely identified 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. The transfusion service medical director must participate in establishing criteria for transfusion and for monitoring of transfusion practices. Nurses and other staff responsible for administering transfusions must complete annual training for the administration of blood and the recognition of transfusion reactions.

**Donor Procedures and Apheresis:** If donors are drawn and/or units are processed at the facility, the inspector will 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.

**Hematopoietic Progenitor Cells:** This section is intended for laboratories involved in the collection, processing, storage, and reinfusion of cellular therapy products, including bone marrow, peripheral blood stem cells, and cord blood. Responsibilities of all parties in the collection, transport, processing, storage and administration of cellular therapy products must be defined. If possible, the inspector will directly observe product collection and processing to verify that actual practice corresponds to the procedure manual. The inspector will confirm that all products and reagents used in the collection are stored properly and that all records are 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 AABB. While compliance with the current edition of the Standards for Blood Banks and Transfusion Services of AABB also represents good laboratory practice, accreditation by 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 the All Common checklist must be addressed to qualify for accreditation by the CAP.
**INSPECTING THE LABORATORY SECTIONS**
**URINALYSIS (URN)**

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimens</td>
<td>111</td>
</tr>
<tr>
<td>Manual Tests</td>
<td>111</td>
</tr>
<tr>
<td>Automated/Semi-Automated Tests</td>
<td>111</td>
</tr>
<tr>
<td>Waived Test Requirements</td>
<td>111</td>
</tr>
</tbody>
</table>

*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 Applicable to All Laboratory Sections.*

**Specimens:** The laboratory must provide instructions for collection of 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 appropriate solutions of known specific gravity and/or refractive concentration index. The laboratory must have written criteria for when a routine urinalysis does not require sediment microscopy. Microscopes must be clean, adequate (eg, low, high dry, and oil immersion lenses), and properly maintained with records 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
- Multiheaded microscopy
- Use of urine sediment photomicrographs with referee and consensus identifications (eg, former CAP Survey, clinical microscopy photomicrographs)
- Digital images

**Automated/Semiautomated Tests:** The laboratory should have written criteria for identifying urine samples that may give erroneous results with a dipstick reader. Automated microscopy systems must be validated or verified, such as through comparison with manual microscopy, before being used for patient reporting. Cell count controls must be processed no less frequently than each day of patient testing.

**Waived Test Requirements:** Certain checklist requirements are different for waived tests and nonwaived tests. Refer to the Inspecting Laboratory Sections - Requirements Applicable to All Laboratory Sections - Waived Test Requirements section of this manual for more information.


**INSPECTING THE LABORATORY SECTIONS**

**REPRODUCTIVE LABORATORIES (RLAP)**

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist Usage</td>
<td>112</td>
</tr>
<tr>
<td>Inspection Process</td>
<td>112</td>
</tr>
<tr>
<td>Procedures</td>
<td>113</td>
</tr>
<tr>
<td>Quality Management</td>
<td>113</td>
</tr>
<tr>
<td>Instrument/Equipment Maintenance</td>
<td>113</td>
</tr>
<tr>
<td>Patient Reports/Records</td>
<td>113</td>
</tr>
<tr>
<td>Personnel</td>
<td>113</td>
</tr>
</tbody>
</table>

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.

**Checklist Usage:** Laboratories in the RLAP have some unique aspects, including:

- Few reproductive laboratories are located in a hospital setting; rather they are typically within physician suites or outpatient surgery centers. As a result, the laboratory must develop many programs that would usually be 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 backup personnel for embryology to ensure patient care needs.
- All routine reproductive laboratory inspections are announced.
- Embryology laboratories are not subject to CLIA; therefore, director requirements for embryology-only laboratories are different from laboratories performing clinical laboratory testing, such as andrology or endocrine testing (refer to the Embryology Personnel section in the Reproductive Laboratory Checklist for the embryology laboratory director requirements).

**Inspection Process:** Inspection of the reproductive laboratory is not limited to the Reproductive Laboratory Checklist. The inspection team must cover the Team Leader, Laboratory General, All Common Checklists, and if applicable to the laboratory to be inspected, the Chemistry and Toxicology Checklists. If additional expertise is required, as for the Chemistry and Toxicology Checklist, the team leader may contact CAP Inspection Assignments at 800-323-4040 for assistance.
During the course of an inspection, the inspector will do the following:

- Observe the testing and processing of specimens submitted for semen analysis and therapeutic insemination. For therapeutic insemination specimens, the inspector will focus on records for verifying and maintaining the identity of the specimen for all processes from receipt to final disposition.
- Observe the processing and cryopreservation of gametes and embryos for assisted reproductive technology procedures (ART). Areas of focus include records for time-out procedures to confirm patient identification prior to initiation of procedures and records for appropriate culture and cryo storage conditions.
- Review a sampling of patient treatment cycle records for completeness and disposition of each gamete and embryo. For reproductive tissues stored in cryo inventory, the inspector will verify that proper labeling and tracking processes are in place.
- If the laboratory is not in a hospital setting, 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, cryopreservation, and storage of tissues. Procedures should include the verification of patient identity and the labeling and tracking of specimens and tissues.

Quality Management: Laboratory director responsibility and oversight must be assessed. There must be evidence that delegated functions are completed by an appropriate designee. The Laboratory General Checklist includes requirements for defining quality indicators for preanalytic, analytic and postanalytic 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 at appropriate rates.

Instrument/Equipment Maintenance: A variety of equipment is used for the testing, processing, and storage of specimens and tissues. The laboratory must define written procedures and have records for routine maintenance and monitoring of all refrigerators, freezers, incubators, and LN2 storage units to detect and prevent equipment failure. It must have a functional backup 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: Patient reports for semen analysis must include the name and address of the laboratory, patient identification, patient results with reference intervals, sperm morphology classification system, and interpretive comments when indicated (e.g., presence of clumps, collection problems). The laboratory must maintain embryology records for each patient treatment cycle, including the timing of events, outcome of insemination, culture, identification of the individual performing each step, disposition of each gamete/embryo, and records of critical supplies and equipment used 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, including minimum educational requirements, specific requirements for training on micromanipulation and other ART-related technologies, and requirements for providing sufficient backup personnel to ensure timely embryology services.
INSPECTING THE LABORATORY SECTIONS
FORENSIC DRUG TESTING LABORATORIES (FDT)

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist Usage</td>
<td>115</td>
</tr>
<tr>
<td>Inspector Requirements</td>
<td>115</td>
</tr>
<tr>
<td>Specimens</td>
<td>115</td>
</tr>
<tr>
<td>Quality Control</td>
<td>115</td>
</tr>
<tr>
<td>Testing Procedures</td>
<td>116</td>
</tr>
<tr>
<td>Personnel</td>
<td>116</td>
</tr>
</tbody>
</table>

*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 Applicable to All Laboratory Sections.*

**Checklist Usage:** The Forensic Drug Testing Checklist is used for laboratories performing nonmedical drug testing including workplace 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 referral laboratory. Testing performed on postmortem toxicology specimens does not meet the eligibility requirements for accreditation under the FDT program.

**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, oral fluid and whole blood samples. If testing is performed on other matrices, 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. Specimens and aliquots must be processed and stored in restricted areas accessible by laboratory personnel only.

**Quality Control:** The laboratory must test QC 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, and at least monthly 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. Certifying Scientists who review and verify analytical data and test results must be appointed by the Scientific Director.
Biorepositories enrolled in the Biorepository Accreditation Program (BAP) are inspected with the Biorepository Checklist and the applicable Biorepository section of the Laboratory General Checklist. All sections of the biorepository must be familiar with and in compliance with the requirements of these checklists.

A biorepository is defined as an entity that receives, stores, processes, and/or disseminates biospecimens, their derivatives, and relative data as needed. It encompasses the physical location as well as the full range of activities.

**Policies and Procedures:** The biorepository must have procedure manuals readily available to staff members in the work areas. Procedures must be reviewed at least every two years by the laboratory director or designee to ensure they are current and reflect actual practice. The biorepository director must review and approve all new and substantially changed procedures prior to implementation. There must be records indicating that the staff members are knowledgeable about the content of procedures applicable to their job responsibilities.

**Quality Management:** The biorepository must have a written and implemented quality management plan specific to the biorepository that includes all processes performed by the biorepository. The biorepository must select quality monitors for preanalytic processes, for QC/quality assurance of stored samples, and distribution processes, as applicable. An effective quality plan includes a system to identify and evaluate errors, incidents, and other problems that may potentially interfere with functions of the biorepository.

**Specimen Handling:** The biorepository must have policies describing the types of specimens that can be submitted. There must be a QC process to ensure the quality of stored specimens. The biorepository must closely monitor and record 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 records 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 recorded in the biospecimen quality assurance 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:** biorepositories 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 the 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.

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 recorded daily. Specimen containers must be approved for their intended use.

The biorepository must have an appropriate thermometric standard device (NIST thermometer) available, and noncertified thermometers must be checked against the thermometric standard device before initial use. Temperatures must be checked and recorded daily, including records that identify the storage unit and location. Temperature alarm limits must be established for each unit, taking into account the time required 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 document that the applications have been tested and approved by the director when first installed and after any changes or modifications. Training of all users must be performed initially upon installation of a new system, and after system modifications or upgrades. There must be a way to track and identify all individuals who have made software modifications. 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. If other computer systems can access the biorepository system, there must be interface security to prevent unauthorized access.
**Inventory System:** There must be an inventory management process, with privilege levels defined for performance of specific functions and access to specific data. The inventory system must be capable of tracking multiple criteria. There must be an audit trail of any changes made to the database. The biorepository must have records of 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. If there is no waiver of consent, all required approvals must be recorded, with appropriate consent. Policies and procedures must be in place ensuring privacy and confidentiality of specimen donors.
INSPECTING OTHER TYPES OF LABORATORIES

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Function Laboratories</td>
<td>120</td>
</tr>
<tr>
<td>Affiliated Laboratories</td>
<td>120</td>
</tr>
<tr>
<td>Satellite Laboratories</td>
<td>121</td>
</tr>
<tr>
<td>Staff-inspected Laboratories</td>
<td>121</td>
</tr>
<tr>
<td>Limited Service Laboratories</td>
<td>121</td>
</tr>
<tr>
<td>System Inspection Option</td>
<td>122</td>
</tr>
<tr>
<td>Features of a System Inspection</td>
<td>122</td>
</tr>
<tr>
<td>System Inspection Preparation</td>
<td>123</td>
</tr>
<tr>
<td>System Inspection Tools</td>
<td>124</td>
</tr>
<tr>
<td>System Summation Conferences and the Global Summation</td>
<td>124</td>
</tr>
</tbody>
</table>

Special Function Laboratories

- Special function laboratories are administered independently of main clinical laboratories and have different CAP numbers and CLIA numbers (if applicable). They generally employ fewer personnel and are dedicated to the performance of a highly select group of clinical procedures. Examples of special function laboratories include, but are not limited to, blood gas laboratories and oncology clinic laboratories.
- If the special function laboratory is within 15 miles or 30 minutes driving distance from the main clinical laboratory, the same inspection team is assigned to perform concurrent inspections. At least four checklists are used for inspection of a special function laboratory—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).
- Compliance with the Team Leader Checklist is evaluated by a peer of the laboratory director, usually the pathologist leader of the overall team.
- Special function laboratories may request their own summation conference.
- The accreditation process and decision for the special function laboratory is independent of the main laboratory’s.
- The responsible hospital administrator and a representative member of the medical staff are 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 CAP number and CLIA number (if applicable). Each site has separate inspection fees, application materials, checklists, and a separate certificate of accreditation.

• Examples of affiliated laboratories include: (a) two or more merged hospitals that provide some services at each site (one often designated as full service and the other as a core laboratory); (b) a large commercial laboratory that has branches in different geographic locations; or (c) remote limited service or special function laboratories.

• **Affiliated laboratories that are within 15 miles or 30 minutes driving distance may be assigned to the same inspection team.** The inspection team leader needs to consider the location of the laboratories in order to allow sufficient time for transportation and inspection.

**Satellite Laboratories**

• Satellite laboratories are usually small branch laboratories that are affiliated with, but not physically located at the same address as the central laboratory. They also have their own CAP numbers and CLIA numbers (if applicable).

• In most cases, the services that are provided correspond with the Limited Service Laboratory Checklist.

• Separate fees, application materials, and checklists are required.

• The inspection can occur concurrently with the main laboratory inspection if the satellite laboratory is within 15 miles or 30 minutes driving distance from the main laboratory. The inspection team leader needs to consider the location of the laboratories in order to allow sufficient time for transportation and inspection.

**Staff-inspected Laboratories**

• This program is in keeping with the CAP’s philosophy of peer review by using CAP-employed medical technologists to review laboratories that are often performing limited testing. These typically include affiliated and/or satellite laboratories that are located more than 15 miles or 30 minutes from the main laboratory.

• Hospitals with 100 beds or fewer that perform basic testing (such as that seen in a core laboratory) may also be inspected by the CAP-employed medical technologists. On-site anatomic pathology services must be limited to frozen sections and/or accessioning to qualify for this type of inspection.

**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 limited number of basic, commonly performed tests covering multiple disciplines. It relieves the inspector and the laboratory of the burden of completing multiple checklists during the on-site inspection.

• If a site qualifies as a limited service laboratory, and it is a free-standing entity with its own CAP number and CLIA number (if applicable), the Laboratory General, Team Leader Assessment of Director & Quality and All Common Checklists are used along with the Limited Service Laboratory Checklist for inspection. 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 CAP and CLIA number, then one copy of the Laboratory General, and Team Leader Assessment of Director & Quality
Checklists are used for both the central laboratory sections and the limited service laboratory. In such cases, the limited service laboratory is viewed as a multifunctional section of the central laboratory.

- The CAP Master Activity Menu is divided into a basic list and an extended list of reportable assays. Use of the Limited Service Laboratory Checklist is determined by the selection of activities performed by the laboratory. Laboratories performing activities limited to the basic list of assays may qualify for the Limited Service checklist. Laboratories performing activities from the extended list use the applicable discipline-specific checklist(s).
- 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.
- If the limited service laboratory performs testing in other laboratory disciplines that can use the Limited Service Checklist (e.g., chemistry, hematology), but there are section-specific requirements that are not specifically represented in the LSV Checklist (e.g., pretransfusion testing, blood storage, coagulation factor assays, chromatography, electrophoresis, microbiology cultures/sensitivities, molecular microbiology, maternal alpha-fetoprotein testing, sweat testing for cystic fibrosis), the section-specific checklist must be used.
- CAP staff make the final determination regarding use of this checklist.

System Inspection Option

Features of a System Inspection

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 that comply with the CAP requirements. It also allows key personnel with responsibilities at multiple sites to participate in each on-site inspection.

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

Each individual laboratory within the system must meet at least seven of the following nine eligibility criteria:
- Operate on the same set of administrative policies and procedures
- Report directly to a central management team
- Perform common competency assessment at each site utilizing a system-wide standardized program
- Participate in a system-wide quality improvement plan
- Use the same QC interpretive standards and guidelines for common instruments and procedures
- Have an integrated information/central data repository or common laboratory information system (LIS)
- Participate in a common safety program with a common safety manual
• Use a common specimen collection manual
• Be located within a three-hour driving distance from the central location (this element is required for all systems)

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

Approximately four to six months prior to the laboratory’s anniversary date, an inspection specialist conducts a pre-inspection conference call to determine the system’s level of integration of services. An on-site pre-inspection visit is scheduled for a group that is new to the CAP’s System Inspection option. The information obtained by the inspection specialist is shared with the team leader and team coordinator to assist with inspection planning and the team building process. This information includes the Planning Guide for Area(s) of Responsibility and the System Pre-Inspection Information form noted in the System Inspection Tools section below.

System Inspection Preparation

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. Once final team count and inspection dates have been approved by CAP headquarters, the CAP Travel Desk staff arranges for direct billing of airfare and lodging and negotiates the best rates for both.

Upon receipt of the inspector’s packet and the pre-inspection report, the team leader will determine the number of inspectors and days needed to complete the inspection. The CAP recommends that inspection teams use inspectors who can inspect multiple areas; this decreases disruption of services at the laboratory and decreases on-site inspection costs. To assemble the team, the team leader references the Planning Guide for Area(s) of Responsibility and the System Pre-inspection Information form sent by the CAP inspection specialist and a team building spreadsheet tool. The team leader shares the plans with the CAP inspection specialist and inspection assignment specialist to determine if there is agreement on team size, composition, time allocation, and the preferred week the inspection will occur.

Inspectors need to prepare for the inspection well before the inspection dates and clarify what is and is not to be inspected. For instance, a system with a central histology/cytology processing location, but with frozen section and/or interpretive services provided at multiple locations requires on-site inspection of each laboratory using the appropriate portions of the Anatomic Pathology and/or Cytopathology Checklists. All Deficiency and Recommendation pages from the Inspector’s Summation Report are to be completed 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 re-inspection(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. For questions on preparing for the inspection or at the time of the on-site inspection, call 800-323-4040 ext. 6065 to consult with a
CAP technical specialist.

**System Inspection Tools**

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 include the following:

1. **Assessment of System Integration form** – This form is completed by the system administration and/or management team at reapplication time. The information will be included in the inspector packet and the criteria can be used to assist in team building. The information can also be included in the global summation conference to discuss degrees of integration for the system.

2. **Planning Guide for Inspector Area(s) of Responsibility** – The team leader uses the Excel spreadsheet to build the team and ensure adequate inspectors are used, as well as ensuring any specialty inspector needs are met. The spreadsheet is customized for the system being inspected.

3. **System Pre-Inspection Information form** – The form is completed by the system administration and/or management team before the pre-inspection call/visit. The inspection specialist reviews the information in the form with the system administration and management team and makes any necessary revisions. The completed form is forwarded to the team leader to assist in team building.

**System Summation Conferences and the Global Summation**

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

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

Inspector’s Summation Report (ISR)

The Inspector’s Summation Report (ISR) is used by an inspector to record the findings of an on-site CAP inspection. It consists of two parts.

Part A – General Summary 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 may be seen by the technical specialist, the state and regional commissioner, a licensing authority as required by law or regulation, and the next inspection team.

The inspector’s confidential comments, listed 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 – Deficiency Summary of the ISR includes the deficiencies (pink pages), and recommendations (yellow pages) recorded by the inspection team and attestation statements signed by the laboratory director and the inspection team leader acknowledging receipt by the laboratory of the ISR Part B. A copy of Part B must be left with the laboratory/biorepository director on the day of the inspection. The inspector must also provide explanatory comments in the ISR regarding unexpected testing encountered, as well as inappropriate checklists included in the packet. The inspector must use only the assigned ISR pages for each discipline. It is not appropriate to cross out sections or include additional checklist titles on the ISR pages. An extra page is included in the ISR packet, which may be copied and used to record additional deficiencies or recommendations. Each inspector must complete the bottom of the deficiency form attesting to the completeness of the inspection, the confidentiality of information, and the lack of a conflict of interest. If multiple inspectors participated in the inspection for the same discipline/checklist, they are to be identified on the reverse side of the form. All original pink and yellow pages of the ISR must be returned to the CAP within two business days of the inspection date. For international inspections, the ISR must be returned within two days after returning to the US.

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

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presummation Team Meeting</td>
<td>126</td>
</tr>
<tr>
<td>Summation Conference</td>
<td>127</td>
</tr>
<tr>
<td>Process and Format of the Conference</td>
<td>127</td>
</tr>
<tr>
<td>Presentation of Deficiencies</td>
<td>127</td>
</tr>
<tr>
<td>Concluding the Inspection</td>
<td>129</td>
</tr>
</tbody>
</table>

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.

**Presummation Team Meeting**

An effective summation conference begins with the presummation 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.

During the meeting, the team should:
- Resolve team members’ questions
- Ensure consistency in recording similar findings (e.g., deficiency versus recommendation)
- Identify serious deficiencies that may jeopardize patient care and systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections
- Review the Part A Questions in the Inspector’s Summation Report

**NOTE:** If serious deficiencies or systemic issues are identified or any question from Part A is answered "NO," cite the appropriate Laboratory General or section-specific checklist requirements relating to the issue, as well as the TLC Checklist requirement(s) related to laboratory director responsibility.

When completing the Inspector’s Summation Report (ISR), the team should:
- Record the deficiencies in a clear, concise, and straightforward manner, relating each to concrete information gathered during the inspection process.
- **List deficiencies on the appropriate pink pages of Part B of the ISR.** 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.** The description should reference specific policies, procedures, analytes, or records to allow 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.
- **List recommendations on the appropriate yellow pages of Part B of the ISR.**
• Copy and use blank ISR deficiency pages and recommendation pages if needed (for instance, reporting the inspection of testing that was not indicated by the laboratory in its reapplication).

• Ensure that all deficiencies being cited have been discussed with appropriate supervisors.
  o If, following this discussion, appropriate records are provided to show the laboratory is actually in compliance, the deficiency should not be cited.
  o 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 laboratory corrected the deficiency); no response required.” The CAP reserves the right to request supporting documentation from the laboratory concerning how the deficiency was corrected on-site.

• Ask the team leader for help in resolving any remaining questions. Technical specialists at the CAP headquarters are also available to assist with questions concerning checklist interpretation during the course of inspection. Call 800-323-4040, between 8:00 AM–5:00 PM Central time.

Before concluding the presummation 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) and recommendation report (yellow 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. Any changes that may have occurred during the presummation conference (addition or changes in deficiencies) are communicated to the appropriate supervisors.
5. The “This laboratory section has no deficiencies” box and/or “No recommendations for this section” box have been checked when applicable.
6. The inspectors have completed and signed the deficiency and recommendations forms and provided contact information on the back of the deficiency form.
7. None of the Part B deficiency (pink sheets) or recommendation (yellow sheets) forms are missing or have been left blank or unsigned. Confirm all deficiency and recommendation pages are accounted for by comparing the returned pages to the list appearing on the pink Inspector Summation Report (ISR) Page Index.

**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 work day.
• 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.
• Each team member should be introduced, noting inspection assignments. This may be done by the team leader or by each team member as they present their report.
• The team leader should state the objective of the CAP’s laboratory accreditation programs, which is 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. To ensure this, it is critical for inspectors to discuss findings with the supervisors, during the inspection and/or at the conclusion of each section.
• Each team member should begin with a brief self-introduction and a word of thanks for the staff that assisted them in the inspection process. Then the team member should present the inspection findings in a brief and professional manner, including the deficiencies identified and areas where the laboratory did particularly well. There should be time to answer questions.
• If TLC deficiencies have already been discussed with the laboratory director, it is not necessary to present these at the Summation Conference.
• 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 recorded 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 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 implementation. Examples of supporting documentation include: policies or procedures edited appropriately and signed and dated by the laboratory director; quality control or maintenance records; log sheets with data; instrument printouts; purchase orders; photographs; memos signed by recipients; meeting minutes with attendance noted; and email 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 reviewing commissioner may reclassify a recommendation when it appears that the item noted should have been cited as a deficiency.
• The written deficiency and recommendation forms constitute the official report of the inspection, and a copy is left with the laboratory. The team leader should provide the envelope that contains the response forms and instructions, and 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 CAP to initiate the laboratory’s corrective action and response to the CAP. The timeframe for receiving an accreditation decision from the CAP is approximately 75 days after the inspection.
• The laboratory should retain a copy of its deficiency responses.
• Both the laboratory director and the inspection team leader must sign page 3 of the ISR-Part A – Deficiency Summary Signature Page at the conclusion of the summation conference.

Concluding the Inspection

*The team leader should:*

• Give an approximation of the total number of checklist requirements that were used to inspect the laboratory so that those in attendance can put the number of identified deficiencies into perspective.
• 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.
• 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.
• 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).
• Complete the Inspector Comments section of Part A of the ISR. Include information on the quality of the laboratory and ability to maintain continuous compliance, any issues of disagreement between the inspector(s) and the laboratory staff, and anything else that may impact on the decision of the regional commissioner to recommend accreditation. Information on travel and accommodations logistics are also helpful, particularly if problems were encountered.
• Place all deficiency (pink) and recommendations (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 two business days of the inspection. This mailer can be used in the 48 contiguous states. Materials from inspections outside the 48 states (ie, overseas countries, Alaska, and Hawaii) should be returned to the CAP in the prepaid envelope after returning to the US. (See Post-Inspection below for details.)
• 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 post-inspection letter thanking the director for the laboratory’s hospitality.

*The CAP performs the remaining steps of the accreditation process:*

• Using the information provided by the inspector, a technical specialist evaluates the deficiency responses for appropriateness and completeness. If additional information is needed to evaluate compliance, a letter is emailed or faxed to the laboratory director, requesting that documentation be sent to the CAP within 10 days.
• When complete, an additional review is performed by 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 or adding a deficiency based on comments included in the Part A Summary in cases where the laboratory was 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, CMS specialties/subspecialties, and requirements for continuing accreditation
3. Final list of deficiencies
4. Press release
POST-INSPECTION FOR THE INSPECTION TEAM

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expense Reimbursement</td>
<td>131</td>
</tr>
<tr>
<td>Team Leader and Team Member Evaluation Forms</td>
<td>131</td>
</tr>
<tr>
<td>Return of the Inspection Packet</td>
<td>131</td>
</tr>
</tbody>
</table>

**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 Inspector’s Summation Report should not be delayed while waiting for the collection of expense information** since this can delay the accreditation process for the inspected laboratory.

The Claim for Inspection Reimbursement form includes instructions for expenses that are reimbursed, maximum allowable expenses, and receipt requirements. 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 each member of the inspection team should complete a Team Member Evaluation questionnaire.

**Return of the Inspection Packet**

To return the inspection report within two business days (with the exception of a non-routine or Florida initial inspection which are to be returned within 24 hours), from anywhere in the US (including Alaska, Hawaii, and Puerto Rico), a UPS prepaid return label is provided:

- Take the shipment to your institution’s mail center for pick-up by UPS, or
- Give the shipment to any UPS driver making a regular pickup, or
- Take it to any UPS authorized shipping location. Use either the UPS website or call 800-PICK-UPS (800-742-5877) for the nearest location.
- For a special pickup, use the website ups.com or call 800-PICK-UPS.

For international shipping, use the website ups.com or call 1-800-782-7892.

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.
Responding to Deficiencies

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

- Set of instructions for completing responses to any deficiencies cited during the inspection
- Blank deficiency response form
- Deficiency response signature page to be signed by the laboratory director and returned with the responses (only one signature page required)
- 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 cap.org. They may be downloaded by logging into the e-LAB Solutions Suite on cap.org and are found under the section CAP Accreditation – CAP Accreditation Resources – Accreditation Forms and Instructions.

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 Inspector’s Summation Report with 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 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 implement or respond to 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
- Sections (or underlined portions) of policies/procedures that pertain to a deficiency
- Quality control, calibration, maintenance records, and instrument printouts
- Log sheets, including recorded data (blank logs are unacceptable)
- Purchase orders, work orders, photos, diagrams, and floor plans
- Evidence of staff review or retraining on new, revised, or existing procedures

Each deficiency requires a separate deficiency response form with appropriate documentation of deficiency correction attached to each. Helpful hints in completing the response include the following:
- List the checklist requirement number on supporting documentation.
- Ensure all documentation is single-sided.
- Avoid using staples, page protectors, or binders (paper clips are preferred).
- Underline appropriate details of the response.
- Do not submit a response for deficiencies noted as “corrected on-site” unless requested by the CAP.
- Do not submit a response for recommendations unless requested by the CAP.
- Retain copies of all documentation submitted for your laboratory/facility records.

For HIPAA compliance, documentation submitted to the CAP must not include any protected health information (PHI), such as patient demographic information. Any patient information must be de-identified in accordance with HIPAA requirements. The following patient data must be de-identified prior to submission:
- Name
- Address
- Any elements of dates, excluding the year, for dates directly related to an individual, including birth date, admission date, discharge date, date of death
- Telephone numbers
- Fax numbers
• Email addresses
• Social Security number
• Medical record numbers
• Health plan beneficiary numbers
• Account numbers
• Biometric identifiers, including finger and voiceprints
• Device identifiers and serial numbers
• Certificate or license numbers
• Vehicle identifiers and serial numbers, including license plate numbers
• Web Universal Resource Locators (URLs)
• Internet protocol (IP) addresses
• Full-face photographs or comparable images
• Any other unique identifying number, characteristic, or code

Challenging a Deficiency

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 (e.g., “I wish to challenge this deficiency.”), with an explanation for the challenge. The laboratory must submit documentation supporting the claim that the laboratory was in compliance prior to the inspection. Supporting documentation is required for challenges to both Phase I and Phase II deficiencies. Challenges must be made at the time initial responses are submitted. 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. In all cases, the inspector must indicate on the Part B deficiency form (ISR) how the deficiency was corrected.

Other more extensive deficiencies, such as the lack of a quality management plan, lapses in performance or review of QC 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, or if previous patient results must be evaluated for any impacts to patient care (e.g., when expired reagents are found to be in
use or when incorrect result calculations are identified), the deficiency cannot be corrected on site. Recurring deficiencies are of significant concern and as such cannot be corrected on site. **Deficiencies corrected onsite 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 report is complete. All deficiency responses and supporting documentation from the laboratory are thoroughly reviewed by a CAP technical specialist. Additional responses or information 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 to complete an additional review. The regional commission will determine if challenged deficiencies will be removed. The regional commissioner may also change a recommendation to a deficiency or add a deficiency based on comments that were included in the Part A Summary in cases where the laboratory was clearly not compliant at the time of the inspection. The review may also involve requests for additional information from the laboratory prior to making an accreditation decision. If the responses adequately address the deficiencies, the regional commissioner will notify the laboratory that accreditation is recommended.

**Immediate Review Criteria**

The CAP’s accreditation programs have established immediate review criteria to 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:

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

**Accreditation**

The 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 responses to Phase I and Phase II deficiencies and satisfactorily documented correction of all Phase II deficiencies. Laboratories granted accreditation may be required to meet additional requirements to maintain accreditation, such as submit records at defined intervals supporting ongoing correction of deficiencies or undergo a successful nonroutine inspection within a specified time period to confirm ongoing compliance. The Accreditation
Committee may also place sanctions (eg, probation) on a laboratory or decide to deny or revoke accreditation.

Upon recommendation of accreditation:
• The official CAP accreditation certificate and accreditation letter is sent from the CAP to the laboratory director, with copies of the letter 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, if a laboratory receives requests from another entity to demonstrate continuing accreditation, a letter may be obtained 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 provided to the next inspection team to confirm continued compliance.

Probation Categories

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

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

1. Facts surrounding the decision to accredit are insufficient to determine compliance.
2. The Accreditation Committee wishes to monitor the progress of the deficiency correction.
3. Laboratory conduct is contrary to the policy of the CAP.
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; for instance:
1. Lack of director oversight
2. Patient/specimen identification issues
3. QC issues that place patients at risk
4. International normalized ratio (INR) issues
The laboratory will have five business days to satisfactorily correct the deficiencies. During the review process, the Accreditation Committee will reconsider the laboratory’s accreditation status, which may and can result in revocation.

**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:
   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 PT program or has failed to meet PT 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 accreditation programs or any other requirement for continued participation in the accreditation programs, and it cannot institute corrective action in the time allowed. The checklists represent the requirements for meeting the *Standards*. Failure to correct cited deficiencies can be the basis for determining that a laboratory does not meet the intent of one or more of the *Standards*.

Laboratories with numerous deficiencies that cannot be corrected within a reasonable period will 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. Agencies applicable to the laboratory accepting CAP accreditation, including but not limited to the CMS or the Joint Commission, will be notified.

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

**Appeals**

The laboratory may appeal denial or revocation within 30 days of receiving written notice of that decision. Appeals must be accompanied by appropriate documentation. A request for reconsideration shall not stay the denial of accreditation. Request for information regarding appeal procedures must be directed to the 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 K- CAP Accreditation Program Policies.*
Post-inspection Critique

Upon receipt of the Inspector’s Summation Report from the team leader, the CAP sends the laboratory director a Post-inspection Critique questionnaire. This questionnaire serves as an ongoing quality assurance tool for the inspection process 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.
Administrative Terms of Accreditation

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

- Cooperate in any CAP investigation or inspection, and promptly notify the CAP if the laboratory becomes:
  - The subject of an investigation by a government entity (including federal, state, local, or foreign);
  - The subject of a validation inspection; or
  - The subject of adverse media attention.
  
  Note: This applies both to laboratories accredited by the CAP and those that have applied for accreditation.

- Promptly notify the CAP 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’s Quality Management Plan.

- Provide a trained inspection team comparable in size and scope to that required for its own inspection, if requested by the CAP, at least once during the two-year accreditation period.

- Participate annually in a CAP-accepted PT program, if applicable; and, if subject to US CLIA regulations, meet the PT requirements in subpart H of the US CLIA regulations.

- Promptly notify the CAP (and, if subject to US CLIA regulations, notify the US Department of Health and Human Services (HHS) in writing 30 days prior to any changes in the following: directorship, location, ownership, insolvency, or bankruptcy.

- Promptly notify the CAP when there is a change in the laboratory’s test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
• Authorize the CAP to release its inspection and PT data and other information required by law to the appropriate regulatory or oversight agencies, such as the CMS, Department of Veterans' Affairs, Department of Defense, Joint Commission, HFAP (AOA), UNOS, or state/provincial agencies.

• If the laboratory is subject to US CLIA regulations:
  o Make available on a reasonable basis the laboratory's annual PT results upon request of any person;
  o Allow HHS or its agent to perform a validation or complaint inspection at any time during the laboratory’s hours of operation and permit HHS to monitor the correction of any deficiencies found through such an inspection;
  o Obtain a CLIA Certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory if it will use CAP accreditation to meet CLIA certification requirements.

• Submit a completed Self-Inspection Deficiency Summary 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 cap.org.

• Submit only documentation and other materials to CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (see 45 C.F.R. § 164.514(b)), unless the laboratory must submit PHI to CAP in order to respond to a deficiency or patient complaint.

• Refrain from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.**

**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 on cap.org.

Use of the CAP Certification Mark of Accreditation

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 cap.org.

Proficiency Testing Participation

The laboratory must participate in a CAP-accepted proficiency testing (PT) program (see glossary for the definition of CAP-accepted PT program) for all required analytes. (For PT enrollment requirements, refer to the Master Activity Menu with PT Options, available through e-LAB Solutions Suite, or the Analyte/Procedure Index section of the CAP Surveys catalog.) 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. PT providers must be contacted 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. Nonparticipation is equivalent to receiving a PT performance score of zero if the laboratory has the activity on their Activity Menu. 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, refer to the CAP’s PT/External Quality Assurance Toolbox available through e-LAB Solutions Suite.

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 performance assessment for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

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 recorded an alternative method to assess its analytic performance for that test. This alternative performance assessment should use the same number of challenges as the missed event.

Alternative performance assessment may include:

- Participation in a PT program (graded or educational) 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
- Clinical validation by chart review, or other suitable and documented means

Alternative performance assessment that allows for comparison of results with an external reference (PT program, split sample with external laboratory, split sample with regional pool) may provide more information than split sample analysis using internal methods. In all cases, acceptability criteria for alternative assessment (e.g., 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. In addition to establishing criteria for alternative performance assessment, the laboratory must troubleshoot any results that fall outside the expected range of acceptability. The laboratory director (or designee) must review and sign off on these results just as with any formal PT evaluation.

Alternative performance assessment must be performed semiannually on tests that do not require enrollment in a CAP-accepted PT program or for which PT is not available.

In some circumstances, certain tests may be performed intermittently, or for a short period of time (e.g., tests done in support of research protocols, or tests related to seasonal diseases such as influenza). In such cases, either PT or alternative performance 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 Accreditation Program continuously monitors proficiency testing (PT) scores from all CAP-accepted PT programs (see glossary for the definition of CAP-accepted PT program) across all testing events for laboratories accredited by the CAP. When unsuccessful PT performance is identified, the PT Compliance Department partners with laboratories to ensure the underlying problem is corrected and the testing is performed in a manner that will not jeopardize patient safety.

Note: Under both CLIA and CAP requirements, failure to participate in a testing event or failure to return results by the due date is equivalent to a zero score for the testing event and is considered unsatisfactory performance. Clerical errors are also considered PT failures.

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. The laboratory must investigate each unacceptable PT result and record the investigation and the specific action taken to prevent recurrence of the problem.

For PTCN’s that do not require a response to the CAP, which includes first time PT failures for most analytes or subspecialties, the inspector will review the documentation of the investigation and corrective action during the on-site inspection.

For subsequent PT failures for the same analyte or subspecialties, the laboratory must complete the PTCN response form and provide documentation of corrective action.

For more information on investigating PT failures, refer to the Inspecting Laboratory Sections – All Common - Investigating PT Failures and Biases & Corrective Action Following a PT Failure section of this manual and the PT/External Quality Assurance Toolbox on e-LAB Solutions Suite.

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

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

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 (PT) 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 tests each patient specimen only once, PT specimens must also be tested only one time. It also means that, over time, 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 laboratory must only report the testing completed in its own laboratory. 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 laboratory director to own or direct a laboratory for two years. CMS-imposed sanctions are presented to the Accreditation Committee for further evaluation. If the CAP substantiates PT referral, the laboratory is presented to the Accreditation Committee for sanctioning.

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

If you have additional questions on PT requirements for breast predictive marker testing (HER2/ER/PgR), refer to the frequently asked questions on cap.org in the PT/External Quality Assurance Toolbox on the e-LAB Solutions Suite.

e-LAB Solutions Suite: Laboratories using CAP Surveys can submit PT results online and view their scores online using the e-LAB Solutions Suite. 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 email (PTCN@cap.org) or fax 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 Deficiency Summary 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 records of corrective action will be kept on file for review by the next CAP inspection team, which will verify that 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 must have a record to demonstrate that personnel responsible for each laboratory section have reviewed the findings of the interim self-inspection. 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. The Joint Commission will occasionally validate the CAP inspection process by sending an observer along with a CAP inspection team. During the hospital's Joint Commission 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.

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

The CAP Laboratory Accreditation Program has been approved as a private accrediting organization under CLIA by the CMS. Therefore, CAP-accredited laboratories may use their CAP inspection in lieu of routine inspection by a CMS agent. This recognition imposes significant obligations upon the accreditation program. 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, (eg, 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 CAP 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.
NONROUTINE INSPECTIONS

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Location, Director, or Ownership</td>
<td>145</td>
</tr>
<tr>
<td>Added Discipline</td>
<td>146</td>
</tr>
<tr>
<td>Secondary On-site Inspection</td>
<td>146</td>
</tr>
<tr>
<td>Proficiency Testing Compliance Notice, Nonroutine Inspection</td>
<td>146</td>
</tr>
<tr>
<td>Complaints</td>
<td>146</td>
</tr>
<tr>
<td>The Complaint Process</td>
<td>146</td>
</tr>
</tbody>
</table>

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 along with an explanation of the additional nonroutine inspection fee will be sent to the laboratory director. The laboratory and the individual(s) 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 30 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 occurred and that all the requirements of the *Standards for Laboratory Accreditation* are met, the commissioner may recommend to waive re-inspection. The laboratory will retain its accreditation until the next regularly scheduled inspection.
Added Discipline

A nonroutine inspection is used routinely for laboratories that add histocompatibility testing.

If the laboratory adds an anatomic pathology or clinical pathology discipline, 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 laboratory 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, a nonroutine inspection will be performed. If a nonroutine 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 confirm compliance or 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 (eg, an 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 of the Commission on Laboratory Accreditation will request this inspection when there is evidence of repeated non-compliance with PT performance standards. A fee is assessed for this inspection.

Complaints

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 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 CAP 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 laboratory, a search of past inspection and PT results, or even an unannounced on-site inspection.

This inspection 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 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 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 includes a brief listing of the most common uses for each checklist. It 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/facility
- Quality management
- Specimen collection
- Direct-to-consumer testing
- Result reporting
- Quality of water
- Laboratory computer services
- Telepathology and remote data assessment
- Whole slide imaging
- Personnel
- Physical facilities
- Laboratory safety

NOTE: The Laboratory General Checklist contains a separate section that applies only to biorepositories enrolled in the Biorepository Accreditation Program.

All Common — used to inspect all laboratory sections
- Proficiency testing
- Procedure manuals
- Specimen collection and handling
- Quality management
- Reporting of results
- Reagents
- Instruments and equipment
- Test method validation/verification
- Reference intervals
- Individualized quality control plan

Anatomic Pathology
- Surgical pathology
- Intraoperative consultation
- Fine-needle aspiration (FNA)
- Histology
• Immunohistochemistry and immunofluorescence microscopy
• In situ hybridization (ISH)
• Digital image analysis
• Circulating tumor cell analysis
• Autopsy pathology
• Electronic microscopy
• In vivo microscopy

NOTE: If FNAs are screened by a cytotechnologist, the Cytopathology Checklist must be used for inspection. Laboratories that only accession tissue specimens should not use the Anatomic Pathology Checklist.

**Biorepository** - for facilities enrolled in the Biorepository Accreditation Program only
• Quality Management
• Biospecimen collection and handling
• Information technology systems
• Inventory management systems
• Storage
• Source and Sponsor facility
• Informed consent and institutional review board
• Distribution policies and agreements

NOTE: Additional requirements for Biorepository inspection are found in the Laboratory General Checklist. The All Common and Team Leader Assessment of Director and Quality Checklists do not apply to biorepositories.

**Chemistry and Toxicology**
• Automated chemistry procedures
• Blood gas analysis
• Therapeutic drug monitoring
• Toxicology screening and confirmatory testing, including legal toxicology
• Prenatal screening
• Cystic fibrosis sweat testing
• Hemoglobin separation
• Methods, such as TLC, GC, HPLC, MS, RIA, and electrophoresis

**Clinical Biochemical Genetics**
• Diagnostic testing for inborn errors of metabolism
• Methods, such as enzyme assays, TLC, GC, HPLC, and MS
• Newborn screening

• **Cytogenetics**  Cytogenetic studies for constitutional and neoplastic disorders
• In situ hybridization ISH)
• Cytogenomic microarray analysis

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

NOTE: Laboratories that only accession cytology specimens should not use this checklist.

Flow Cytometry
• Blood lymphocyte subset enumeration
• CD34 stem cell enumeration
• Leukemia and lymphoma immunophenotyping
• DNA content and cell cycle analysis

Forensic Drug Testing – for laboratories enrolled in the Forensic Drug Testing Accreditation Program only
• Nonmedical drug testing
• Screening and confirmatory testing for different specimen types
• Specimen handling and chain of custody
• Certification/inspection of results
• Methods, such as immunoassays, LC, GC, and MS

Hematology and Coagulation
• CBC and differentials, automated and manual
• Reticulocytes, automated and manual
• Bone marrow preparations
• Abnormal hemoglobin detection
• Blood film examination for malaria and other parasites
• Body fluid cell counts (automated and manual) and differentials
• Semen analysis
• Routine coagulation assays
• Specialized coagulation assays, including factor assays, mixing studies, D-dimer, and platelet function assays

Histocompatibility
• HLA testing by serologic, molecular, flow cytometry, ELISA, and solid phase methods
• Class I and II antigen typing
• HLA antibody screening, identification, and crossmatching
• DNA typing, including generic, high resolution, and DNA sequence-based typing
• Donor-recipient histocompatibility, including renal, stem cell, and nonrenal
transplants
• Monitoring for engraftment (chimerism)

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

**Immunology**
• General immunology assays, manual and automated
• Immune system profiles
• Microbial antigen/antibody testing
• ABO/Rh and antibody screening (non-transfusion-related)
• Syphilis serology by fluorescent and/or serologic methods
• Western blot

**Limited Service Laboratory** — used to inspect 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 contains a limited subset of requirements from other checklists.
• Automated and manual hematology testing, including CBC, reticulocytes, and differentials
• Routine coagulation assays
• Body fluid analysis, including semen analysis
• Automated general chemistry
• Blood gas analysis
• Therapeutic drug monitoring
• Screening for drugs of abuse
• Urinalysis dipstick and microscopy, manual and automated methods
• Microbiology specimen setup, direct specimen examination, stains, and antigen typing for various subdisciplines
• General immunology assays, including immune system profiles and microbial antigen/antibody testing, non-transfusion-related immunohematology testing, and syphilis serology

NOTE: 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, virology, and molecular
microbiology, including DNA testing using amplified and non-amplified 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 (non-transfusion), and direct antiglobulin testing
- Separate discipline-specific checklists are required for: anatomic pathology, clinical biochemical genetics, cytopathology, cytogenetics, histocompatibility, flow cytometry, molecular pathology, and point-of-care-testing

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

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

**Molecular Pathology**
- Clinical molecular genetics testing, including oncology, hematology, inherited disease, pharmacogenomics, HLA typing, forensics, and parentage applications
- Molecular assay validation
- Methods, such as electrophoresis, PCR, arrays, in situ hybridization, and sequencing
- Next-generation sequencing, including noninvasive screening of maternal plasma to detect fetal aneuploidy

**Point-of-Care Testing** — used for the inspection of testing performed at or near the site where the patient is located only (with non-dedicated space)
- Kit tests or hand-carried instruments (or otherwise transported to the patient location)
- Waived and moderate-complexity testing
- Point-of-care testing (POCT) blood gas analysis
- D-dimer studies
- Provider-performed testing that is under the responsibility of the laboratory director

**NOTE:** A discipline-specific checklist(s) may be required in addition to the Point-of-Care Testing Checklist if certain analytes warrant its use. Laboratories with fixed dedicated testing space require either a Limited Service Checklist or additional discipline-specific checklist(s). A separate checklist must be completed for each POCT location when POCT records are not maintained in a central location.
Reproductive Laboratory – for laboratories enrolled in the Reproductive Laboratory Accreditation Program only

- Complete semen analysis, automated and manual methods
- Biochemical testing
- Antisperm antibody testing
- Sperm processing for therapeutic insemination
- Embryology procedures
- Embryo and gamete cryopreservation
- Reproductive tissue programs

Team Leader Assessment of Director & Quality — used by the inspection team leader to evaluate the effectiveness of the director in implementing the Standards of the Laboratory Accreditation Program

- Laboratory director qualifications
- Laboratory director responsibilities
- Laboratory directors not present full-time in the laboratory

Transfusion Medicine

- Immunohematology testing, manual and automated
- Compatibility testing, including computer crossmatches
- Perinatal testing
- Transfusion procedures and adverse reactions
- Therapeutic phlebotomy
- Donor and therapeutic apheresis
- Component preparation, storage, and modification
- Bone marrow and/or hematopoietic progenitor cell services
- Tissue storage and issue
- Donor selection, collection, and testing

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

Urinalysis

- Urinalysis dipstick, automated and manual methods
- Manual urine microscopy
- Automated microscopy systems
Appendix B: Guidelines for Determining Test Volume

Test volumes must be reported 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), QC, quality assurance, proficiency testing assays or tests routinely sent out to a referral laboratory.

Note: For international laboratories (including Canada) that have a CLIA certificate, only the test volume for moderate- and high-complexity testing performed on patient specimens received from the US should be reported in the CMS reporting area.

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

**Specialty information:**

**Chemistry:** For profiles, each noncalculated analyte is counted separately (e.g., a Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals four tests).

**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 manual gynecologic and nongynecologic cytology, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology. Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide. For gynecologic slides screened by automated screening instruments where only a portion of the slide is reviewed, refer to the manufacturer’s product insert to determine how to count test volume.

**Flow Cytometry:** Each measured individual analyte (e.g., T cells, B cells, CD4, etc.) that is ordered and reported is counted separately.

**Hematology:** Each measured individual analyte of a complete blood count (CBC) that is ordered and reported is counted separately. White blood cell differentials count as one test.

**Histocompatibility:** Each HLA typing (including disease-associated antigens), each HLA antibody screen, and each HLA crossmatch is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as three tests.

**Histopathology:** For CMS statistics, each block (not slide) is counted as one test. For laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains, including immunohistochemistry, performed on slides to
the total number of specimen blocks prepared by the laboratory. Autopsy services should be included in the “CMS-nonreported” category.

**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 test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.

**Molecular Pathology:** For genetic tests, every test ordered is counted as one test with one report. For **Next Generation Sequencing**, every test ordered (eg, a gene panel, exome or genome) is counted as one test with one report.

**Point-of-Care Testing:** Point-of-Care (POC) testing should be counted according to the specialty of the test. For example, if a prothrombin time is done as part of point of care it would be counted the same as if it were done in a coagulation department. Similarly, a macroscopic (dipstick) urinalysis test done as part of POC should follow the urinalysis criteria listed below. Laboratories should also count nonwaived POC tests as CMS-reported while waived POC tests are counted as CMS-nonreported.

**Urinalysis:** Microscopic and macroscopic examinations each count as one test. Macroscopics (dipsticks) are counted as one test, regardless of the number of reagent pads on the strip.
Appendix C:
Announced and Unannounced Inspections: Tips for Laboratories and Site Coordinators

Tips for Laboratories

What Is a Site Coordinator?

The site coordinator (SCO) 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 well in advance of the inspection 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.

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 blackout 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 pre-inspection 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 accommodated
  • 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 laboratory 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 laboratory 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.

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 cap.org.
Appendix D:
Sample of Inspection Confirmation Letter to Laboratory Director

This letter should be used for announced inspections, and may be used for unannounced inspections as long as the inspection date is not disclosed. 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 (...). (Include date(s) for announced inspections only.)

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 records supporting compliance with the checklist requirements readily available. As we go through the checklists, we will review the following:

1. Laboratory General
   a. Specimen collection manuals (electronic or paper) and examples of requisitions
   b. Personnel policies and complete personnel records, including training, competency assessment, changes to the Laboratory Personnel Evaluation Roster (gathered and organized at one site that is convenient to the laboratory)
   c. Qualifications of all testing personnel and supervisory personnel (diplomas, transcripts, state licensure, board certification, primary source verification reports, equivalency evaluation for foreign trained personnel, as applicable)
   d. Quality management plan and records of quality indicator monitoring, meetings, studies, etc
   e. Self-inspection records from last year (does not apply to initial CAP inspections)
f. Safety manual and records of training, safety reviews, evaluation of incidents (bloodborne pathogens, other infectious hazards, chemicals, fire, environmental, etc)
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. Examples of patient test reports, including corrected reports
j. LIS manual and records of system testing and maintenance (LIS staff should be available on the day of the inspection)

2. **Team Leader Assessment of Director and Quality**
   a. Laboratory director qualifications
   b. Record of delegation of responsibilities
c. Job description or agreement for frequency of visits, as applicable
d. Records of laboratory director involvement

3. **Each section/department**
   a. Proficiency testing records
   b. Specimen labeling policy and rejection criteria
   c. Procedure manuals
d. Critical result policy and records of notification
e. New reagent lot studies
f. Instrument function check maintenance records
g. Temperature-dependent equipment and environment monitoring records, including thermometer certification
h. QC, including individualized quality control plan forms and records
i. Test validation and verification records for all analytes

4. **Hematology**
   Example slides of white blood cell differential, bone marrow, and reticulocyte stains

5. **Microbiology**
   Example slides of Gram stain and other stains

6. **Chemistry**
   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)
11. Transfusion Medicine
   Blood and component storage records, blood administration procedures, audits of blood
   issue and administration process, pretransfusion testing and transfusion records, adverse
   reactions and incident investigations, blood donation procedures and records, and
   transfusion committee meeting minutes

12. Point-of-Care Testing (POCT)
   QC records, instrument records, list of personnel authorized to perform POCT, personnel
   training and competency records (all organized at one location for all test sites)

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 and administration 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.

Sincerely,

_______________________________________
Team Leader's Name
<table>
<thead>
<tr>
<th>Activity Code</th>
<th>Activity Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4467</td>
<td>Autoverification</td>
<td>The process by which patient results generated from interfaced instruments and sent to the laboratory information system (LIS) are compared against laboratory-defined acceptance parameters. Results within the parameters are automatically released without laboratory staff intervention.</td>
</tr>
<tr>
<td>326</td>
<td>Bar-coded specimen processing</td>
<td>Use of an electronically generated bar-code label for patient samples during the collection and/or testing process.</td>
</tr>
<tr>
<td>4462</td>
<td>Blood and/or clinical specimen collection service</td>
<td>Blood and/or clinical specimen collection services are provided by personnel under the control of the laboratory director.</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>3551</td>
<td>Direct-to-consumer (DTC) testing</td>
<td>Testing that is requested or ordered by the consumer.</td>
</tr>
<tr>
<td>325</td>
<td>Information system interface(s)</td>
<td>Results are transmitted directly from instruments through middleware or through data handling software to a laboratory or hospital information system.</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>5229</td>
<td>Laboratory information system – none</td>
<td>Laboratory does not have an LIS.</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>4469</td>
<td>Moderate/high complexity testing</td>
<td>Laboratories performing either moderate- or high-complexity testing (non-waived testing)</td>
</tr>
<tr>
<td>5267</td>
<td>No clinical diagnostic testing</td>
<td>Testing that does not require a CLIA certificate (processing only, embryology, forensics, research only)</td>
</tr>
<tr>
<td>4470</td>
<td>PPM Testing</td>
<td>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>ID</td>
<td>Description</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</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>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>4460</td>
<td>QMS not integrated with other lab</td>
<td>The quality management system is independent of other laboratories.</td>
</tr>
<tr>
<td>328</td>
<td>Specimen accessioning</td>
<td>The receiving, sorting, and logging of specimens into an LIS or other record</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>5167</td>
<td>Specimen collection for newborn screening, blood spot</td>
<td>Collection of a blood sample on a filter paper for routine newborn screening for congenital disorders</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>5473</td>
<td>Specimen referral for newborn screening, blood spot</td>
<td>The laboratory refers newborn screening blood spot sample to other testing laboratory for analysis.</td>
</tr>
<tr>
<td>4461</td>
<td>Specimen referral to another laboratory</td>
<td>The laboratory sends specimens to other testing laboratories for analysis.</td>
</tr>
<tr>
<td>4465</td>
<td>Specimen transport to/from other laboratory</td>
<td>Patient samples are transported and received from remote locations outside of the laboratory or are transported by the laboratory to other locations.</td>
</tr>
<tr>
<td>4468</td>
<td>Telepathology</td>
<td>A pathologist examines digitized or analog video, still image(s), or other data files (eg, flow cytometry files, Sanger sequencing data) at an off-site or remote location and an interpretation is rendered that is included in a formal diagnostic report or in the patient record. It also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record.</td>
</tr>
<tr>
<td>4457</td>
<td>Waived complexity testing</td>
<td>Testing that is limited to waived methods as defined by the CLIA regulations</td>
</tr>
<tr>
<td>5595</td>
<td>Whole slide imaging</td>
<td>The use of a whole slide imaging system for diagnostic purposes (primary and/or consultation)</td>
</tr>
</tbody>
</table>
Appendix F:
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 (suspicous-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/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 (Gram, trichrome, etc)</td>
<td>7 days</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><strong>Blood Bank</strong></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 (e.g., 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 G: Glossary of Terms

Accepted PT Provider
A proficiency testing (PT) 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.

Accreditation Checklist
A detailed series of requirements through 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; however during the review process, a need has been identified for an interim follow-up assessment to monitor ongoing compliance.

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

Activity Menu, Master
The list of all tests and 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.
Addendum
Information added to a verified final report that leaves the original report intact and unchanged.

Alternative Performance Assessment
egA system for determining the reliability of laboratory examinations when participation in proficiency testing is not required for an analyte by the accrediting organization, for which no commercial proficiency testing products are available, or are not appropriate for the method or patient population served by the laboratory.

Amended/Amendment
Any change in the diagnosis, narrative text, or other content of a report that has been issued (minor or major). The change in an anatomic pathology report is usually in the diagnosis or narrative, but occasionally may involve a change in a number or some other quality.

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.

Analytical 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.

Analytical 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.

Analytical Validation
The process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application.

Analytical Verification
The process by which a laboratory determines that an unmodified FDA-cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed.

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 reapplyes or (under some circumstances) is in the process of accreditation. The anniversary date is fixed and biennial (occurring every two years).

Annual
Every 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.

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

Biennial
Every 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 test system.

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 laboratory’s effectiveness and contribution to the quality of patient care.
• CAP 15189 does not replace the CAP’s CLIA-based Laboratory Accreditation Program, but rather complements CAP accreditation and other quality systems.

CAP-accepted PT Programs
Proficiency testing (PT) programs which have met the CAP’s criteria. Acceptance criteria are by analyte only and should not infer the entire program.

• For laboratories subject to US regulations, participation in proficiency testing may be through CAP PT Programs or another PT provider accepted by CAP.
• For laboratories not subject to US regulations, participation in PT must be through CAP PT Programs only. 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 the supervision of the discipline. The regional commissioner will use this data to evaluate whether the discipline can be accredited without a nonroutine inspection.

Check
Examination to determine the accuracy, quality, or presence of any attribute of a test system.

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.

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

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

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

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

Clinical Validation
The determination of the ability of a test to diagnose or predict risk of a particular health condition or predisposition, measured by sensitivity, specificity, and predictive values.

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). 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, or the inspection process.

Commissioner, Deputy or Division or State
Individuals responsible for the assignment of inspection team leaders.

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

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.

Commutable
The property of a reference material that yields the same numeric result as would a patient's specimen containing the same quantity of analyte in the analytic method under discussion (ie, matrix effects are absent).

Confirmation
Substantiation of the correctness of a value or process.

Consultant
One who provides professional advice or services on request.

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

Corrected/correction
Errors in test results that may include incorrect patient identification, test results, reference interval, interpretive information, or other significant information, but not minor typographical errors of no consequence.

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

Correlation
Establishment of agreement between two or more measured values.
Council on Accreditation
A CAP council that formulates policy for and oversees the work of the Commission on Laboratory Accreditation.

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

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

Critical PT Performance (Regulated analytes)
See Repeat Unsuccessful PT Performance (Cease Testing)

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 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.
Device
Any reagent, reagent product, kit, instrument, apparatus, equipment, or related product, whether used alone or in combination, intended by the manufacturer to be distributed for use in vitro for the examination of human specimens.

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

Director of Laboratory
See Laboratory Director.

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

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

Equipment
Single apparatus or set of devices or apparatuses needed to perform a specific task.

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, exclusive of any deficiencies that were expunged during the post-inspection process.
Forensic Drug Testing (FDT)
The CAP accreditation program for laboratories that perform drug testing for nonmedical purposes (e.g., workplace drug testing).

FDT
See Forensic Drug Testing.

Function Check
Confirmation that an instrument or item of equipment operates according to manufacturer's specifications before routine use, at prescribed intervals, or after minor adjustment (e.g., base line calibration, balancing/zero adjustment, thermometer calibration, reagent delivery).

General Supervisor
A position defined by the Clinical Laboratory Improvement Amendments (CLIA) of 1998 as the individual who provides day-to-day supervision of testing personnel and reporting of testing results in a laboratory that performs high-complexity testing.

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

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 Accreditation Unit cycle, there is one inspection event for every section unit.

Inspection Instance (II)
A numerical identifier for each inspection that groups together Accreditation Units and Section Units (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 checklists, laboratory synopsis reports, the Laboratory Accreditation Manual, Inspector’s Summation Report forms, etc.

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

Instrument
An analytical unit that uses samples to perform chemical or physical assays (e.g., chemistry analyzer, hematology analyzer).

Instrument Platform
Any of a series of similar or identical analytical methods intended by their manufacturer to give identical patient results across all models

IRC Laboratory
See Immediate Review Criteria.

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

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)
For the purposes of interpreting the checklist requirements, a laboratory-developed test (LDT) is defined as follows: A test used in patient management that has both of the following features:
1. The test is performed by the clinical laboratory in which the test was developed wholly or in part; AND
2. The test is neither FDA-cleared nor FDA-approved.
License
Right or permission granted in accordance with the law by a competent authority to engage in some business or occupation, which, but for such license, would be unlawful. For laboratories, a license may be granted by a municipal, state, or federal authority. For physicians, in the United States, a license is granted by the State Board of Medical Examiners.

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

List of Deficiencies
A listing of the checklist requirements that were established as deficiencies at an inspection of a specific accreditation unit.

Maintenance
Those activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning or changing parts, fluids, tubing, lubrication, electronic checks, etc.

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, as applicable; 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 analytical validity may be used to refer to 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 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+).

Analytical 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.

Analytical 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 QC, 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.

Moderate Complexity
The rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health.

Modification of Manufacturer's Instructions
Any change to the manufacturer's supplied ingredients or modifications to the assay as set forth in the manufacturer's labeling and instructions, including specimen type, instrumentation, or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results.

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 FDA, according to a scoring system used by the FDA.

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

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

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

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

Performance verification
The set of processes that demonstrate an instrument or an item of equipment operates according to expectations upon installation and after repair or reconditioning (eg, replacement of critical components).

Physician
An individual who has received a doctor of medicine or osteopathy degree and who is currently fully licensed by a state medical board 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.

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

Postanalytic Phase (postexamination process)
Processes following the analysis (examination) of patient specimens, including review, formatting, interpretation, verification, reporting and transmission of the results, and storage of samples and results.
Preanalytic Phase (pre-examination process)
Processes prior to the analytic examination of patient specimens, including, in chronological order: the clinician’s request, test order, preparation of the patient, collection of the primary sample, transportation to and within the laboratory, and sample preparation.

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

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

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

Primary Specimen
The body fluid, tissue, or sample submitted for examination, study, or analysis. It may be within a collection tube, cup, syringe, swab, slide, data file, or other form as received by the laboratory.

Probation
An accreditation status assigned by the Accreditation Committee if any of the following inspection findings exist:
- Documentation is insufficient to determine compliance with the CAP’s standards within the Standards for Laboratory Accreditation.
- The committee wishes to monitor the laboratory’s progress in correcting deficiencies.
- The laboratory has engaged in conduct contrary to the policies of the CAP but such conduct is not sufficient to warrant denial or revocation of accreditation.
A laboratory on probation may continue to provide testing as an accredited laboratory.

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

Procedure
1) Specified way to carry out an activity of a process (also referred to by ISO as "work instructions"); 2) Set of steps performed that tells "how to do it" to achieve a specified outcome, including decisions to be made.
**Process**
1) Set of interrelated or interacting activities that transforms inputs into outputs; 2) Series of events, stages, or phases that takes place over time that tells "what happens" or "how it works."

**Proficiency Testing**
Evaluation of participant (laboratory or individual) performance against pre-established criteria by means of interlaboratory comparisons. In some countries, the PT programs for clinical laboratories are called "external quality assessment" programs.

**Proficiency Testing (PT) (Also termed: External Quality Assessment [EQA])**
The determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification. The program then compares each laboratory’s results with those of other laboratories in the group and/or with an assigned value. Proficiency testing serves the purposes of education, laboratory improvement, and regulation.

**Proficiency Testing Compliance Notice (PTCN) – Non-enrollment**
A notice issued by the CAP Accreditation Program identifying when the laboratory is not enrolled in proficiency testing for a required analyte that is on the laboratory’s activity menu. Nonparticipation in a PT event is equivalent to a performance score of zero.

**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 Accreditation Program did not receive a score from the PT provider. Nonparticipation monitoring is a continuous process and nonparticipation in a PT event is equivalent to a performance score of zero.

**Proficiency Testing Compliance Notice (PTCN) – Performance**
A notice issued by the CAP Accreditation Program identifying performance for an analyte or subspecialty that does not meet the criteria for acceptable PT performance. When appropriate, a summary of scores for the most recent four PT testing events is included with the PTCN.

**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 of action taken when performance does not conform to standards set by the laboratory. QC is a set of procedures designed to monitor the test method and the results to assure test system performance; QC includes testing control materials, charting the results and analyzing them to identify sources of error, and determining, performing, and documenting any remedial action taken as a result of this analysis.

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

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

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.

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.

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

**Report Error**
A report element (see GEN.41096) that is either incorrect or incomplete.

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

**Required Analyte**: An activity for which the CAP Accreditation Program requires PT enrollment and participation. Both waived and nonwaived activities are included in the list of required analytes.

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

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

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

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

**RLAP**
See *Reproductive Laboratory Accreditation Program*.

**Scientific Director**
A laboratory-appointed director associated with an Accrediation Unit (Forensic Drug Testing only).

**Secondary Specimen**
Any derivative of the primary specimen used in subsequent phases of testing. It may be an aliquot, dilution tube, slide, block, culture plate, reaction unit, data extract file, image, or other form during the processing or testing of a specimen. (The aliquots or images created by automated devices and tracked by internal electronic means are not secondary specimens.)

**Section Director**
The individual who is responsible for the medical, technical, and/or scientific oversight of a specialty or section of the laboratory.
Section Unit (SU)
An operational area or department of an Accreditation Unit, 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
Every six 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) and conducts inspections on behalf of the CAP.

Standards
The Standards for Laboratory Accreditation as published by the CAP Council on Accreditation. The Standards are the core principles of the CAP’s laboratory accreditation programs.

SU
See Section Unit.

Subdiscipline
A CAP-defined term used to describe related testing activities that reside under a particular discipline.

Subject to US Regulations
Laboratories located within the United States, and laboratories located outside of the US that have obtained or applied for a CLIA certificate, to perform laboratory testing on specimens collected in the US for the assessment of the health of human beings.
Supervisor
A person responsible for the daily activities of a section unit.

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

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

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

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

Telepathology
The practice 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 is recorded 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. Reasons for termination include:

- Denial of an accreditation unit’s (AU) 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.
- Failure to return reapplication materials within a specified time frame. The termination will occur after reminder options have been exhausted. Letters will be sent to the AU and the regional commissioner stating that the laboratory has been terminated because completed reapplication materials were not returned to CAP.
- Merger of two or more 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**
A qualitative, semiquantitative, quantitative, or semiquantitative procedure for detecting the presence of, or measuring an analyte

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

**Testing Personnel**
Individuals responsible for performing laboratory assays and reporting laboratory results.

**Test System**
The process that includes preanalytic, analytic, and postanalytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use, and can include reagent 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 (PT) Performance**
Failure to attain at least 80% for a regulated analyte/subspecialty/specialty (ABO, Rh, and Compatibility Testing requires 100%) for a testing event. Clerical errors or data omissions are considered PT failures. For nonregulated analytes, satisfactory performance will vary based on the number of challenges. Refer to the CAP’s PT/External Quality Assurance Toolbox available through e-LAB Solutions Suite for more information.

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

**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 Clinical Laboratory Improvement Amendments of 1988 as “simple laboratory examinations and procedures which have an insignificant risk of an erroneous result.” Laboratories performing waived tests are subject to minimal regulatory requirements.

For laboratories subject to US regulations, these tests are assigned to the waived category by the US Food and Drug Administration (FDA).
Appendix H:
Accreditation Requirements When a Proficiency Testing Result Is Linked to an Exception Reason Code

The CAP uses Exception Reason Codes to signify that 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. Your 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. 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 methods, or all participant statistics if provided. If comparison is not available, perform and document alternative assessment (eg, split samples) 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>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 it were unacceptable and review the proper reference documents to gain knowledge of the reason your response is not appropriate.</td>
</tr>
<tr>
<td>26</td>
<td>Educational challenge</td>
<td>Response to the CAP is not required. Laboratory should document its review.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Action</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------</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 replacement specimens were available. Perform and document alternative assessment (eg, 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 (eg, 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>Document that the laboratory performed a self-evaluation of written protocols and practices for</td>
</tr>
<tr>
<td>42</td>
<td>No credit assigned due to absence of response</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 the 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>44</td>
<td>This drug is not included in our test menu. Use of this code counts as a correct response.</td>
<td>Verify that the drug is not tested on patient samples and document to ensure proper future reporting.</td>
</tr>
<tr>
<td>45</td>
<td>Antimicrobial agent is likely ineffective for this organism</td>
<td>Document that the laboratory performed a self-evaluation of written protocols and practices for</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Response</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------</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>
Appendix I:
CAP Accreditation Program Policies (August 2016)

Table of Contents

1. ACCREDITATION
   1.01 REQUIREMENTS FOR ACCREDITATION
   1.02 ACCREDITATION FEES
   1.03 PARTICIPATION IN PROFICIENCY TESTING
   1.04 ACCREDITATION CHECKLISTS
   1.05 RELEASE OF ACCREDITATION INFORMATION
   1.06 NEWS MEDIA INQUIRIES
   1.07 CORRECTION OF DEFICIENCIES
   1.08 REVOCATION OR DENIAL OF ACCREDITATION
   1.09 ACCREDITATION WITH REQUIREMENTS
   1.10 TERMS OF ACCREDITATION
   1.11 LAPSE OF ACCREDITATION
   1.12 CHANGE OF DIRECTOR
   1.13 CHANGE OF OWNERSHIP OR LOCATION
   1.14 REVISION OF STANDARDS
   1.17 INVESTIGATION OF COMPLAINTS
   1.18 WITHDRAWAL FROM THE CAP ACCREDITATION PROGRAMS
   1.19 CONFLICT OF ACCREDITATION REQUIREMENTS WITH PREVAILING LAW OR REGULATION
   1.20 ELIGIBILITY OF LABORATORIES
   1.21 ACCREDITATION WITH PROBATION
   1.22 PROTECTION OF COMPLAINANTS OR WHISTLE-BLOWERS
   1.23 MISREPRESENTATION BY A PARTICIPATING LABORATORY
   1.24 INVESTIGATIONS AND MEDIA ATTENTION
   1.25 PRELIMINARY ACCREDITATION
   1.26 PROFICIENCY TESTING PROGRAMS
   1.27 DENIAL OF ELIGIBILITY AFTER APPLICATION FOR ACCREDITATION
   1.28 DEFERRAL OF INITIAL ACCREDITATION DECISION
1.29 ACCREDITATION PROGRAMS FIREWALL FOR CAP-APPROVED PROFICIENCY TESTING PROVIDERS’ DATA AND INFORMATION

1.30 DEFICIENCIES

1.31 USE OF THE NAME AND LOGO OF THE CAP BY LABORATORIES

1.32 USE BY AN ACCREDITED LABORATORY OF THE CAP NUMBER ON REPORTS CONTAINING RESULTS FROM TESTS OUTSIDE THE CAP’S AREAS OF MEDICAL EXPERTISE

1.33 LABORATORY DIRECTORSHIP LIMIT

1.34 CONTINUING ACCREDITATION IN THE ABSENCE OF AN ON-SITE INSPECTION

1.35 POST-INSPECTION REVIEW AND ACCREDITATION DECISION IN THE ABSENCE OF AN ON-SITE INSPECTION

1.36 ACCREDITATION OF LABORATORIES NOT PERFORMING TESTING

2. INSPECTION

2.01 CONFLICTS OF INTEREST

2.02 SIZE AND COMPOSITION OF THE INSPECTION TEAM

2.03 NON-ROUTINE INSPECTIONS

2.04 LABORATORY SELF-INSPECTIONS

2.05 CONFIDENTIALITY OF INSPECTION FINDINGS

2.06 APPEAL OF INSPECTOR ASSIGNMENTS

2.07 USE OF CHECKLISTS

2.08 SOURCE OF INSPECTION TEAM

2.09 INTENTIONALLY LEFT BLANK

2.10 ROUTINE INSPECTIONS

2.11 “DO NOT USE” STATUS OF INSTITUTIONS AND INSPECTORS

2.12 LIMITED SERVICE TESTING

3. INSPECTORS

3.01 REIMBURSEMENT OF TRAVEL EXPENSES FOR CAP INSPECTIONS

3.02 INSPECTION TEAM LEADERS, INSPECTION TEAM MEMBERS, AND INSPECTION TEAM COMPOSITION

3.03 INSPECTOR TRAINING REQUIREMENTS

3.04 INTERNATIONAL INSPECTION TRAVEL AND ASSIGNMENTS
1. **ACCREDITATION**

1.01 **Requirements for Accreditation**

1.01. a. To be considered for accreditation by the CAP, a laboratory must submit an appropriately completed application and necessary deposits or fees.

1.01. b. To be accredited by the CAP, 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. c. For each two-year accreditation period (for laboratory accreditation) or each three-year accreditation period (for biorepository accreditation), a laboratory must provide a qualified 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. d.1. Laboratories located outside the United States, Mexico and Canada will be required to pay round trip business class airfare for inspectors, at the discretion of the chair of the commission, in addition to any ordinary accreditation fees if an inspector from another country is assigned.

1.01. d.2. Laboratories located within the United States, Mexico and Canada will not be required to pay travel expenses for inspectors.

1.01.e. A laboratory must submit to a complete inspection.

1.01.e.1. For any laboratory subject to CLIA, the CAP will inspect and accredit all testing and activities performed under the laboratory’s CLIA number that generates results used in, or that directly impacts, patient care or the assessment of the health of human beings. This includes tests used in the diagnosis and treatment of patients in clinical trials.

1.01.e.1.a. For any laboratory subject to CLIA, the CAP will assign a CAP number for all testing and activities performed under the laboratory’s CLIA number.

1.01.e.1.b. If an institution has more than one CLIA number for laboratories located in its building or campus (ie, one or more affiliated laboratories with its own CLIA number), each CLIA number is considered a single laboratory.

1.01.e.1.b.i. Each laboratory with its own CLIA number that desires to be CAP accredited must individually apply for accreditation and obtain its own CAP number.

1.01.e.1.b.ii Each CAP number will be inspected with its own set of accreditation checklists corresponding to the testing and activities performed under its respective CLIA number.

1.01.e.1.c. All affiliated laboratories at the same location that desire to be CAP accredited may be inspected during the same inspection event.

1.01.e.1.d For any laboratory subject to CLIA, the individual serving as laboratory director for
purposes of CAP accreditation must be named as laboratory director on the laboratory’s CLIA certificate. Exceptions may be made based on circumstances.

1.01.e.2. For any laboratory 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 campus. Exceptions may be made based on circumstances.

1.01.e.3. 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, including testing or activities performed in areas or structures adjacent to or within 250 meters of the laboratory’s main building(s). Exceptions may be made based on circumstances.

1.01.e.4.a. If a laboratory fails to identify any testing or activities performed under its CLIA number, the Accreditation Committee or the reviewing commissioner may elect to conduct a non-routine inspection of the testing or activities at the laboratory’s expense.

1.01.e.4.b. If a laboratory not subject to CLIA fails to identify any testing or activities performed under the same director, same laboratory name, and same campus, the reviewing commissioner may elect to conduct a non-routine inspection of the testing or activities at the laboratory’s expense.

1.01.e.4.c. If a laboratory located outside of the United States and not subject to CLIA fails to identify testing or activities performed in areas or structures adjacent to or within 250 meters of the laboratory’s main building(s), the reviewing commissioner may elect to conduct a non-routine inspection of the testing or activities at the laboratory’s expense.

1.01.f Special Function and Other Affiliated Clinical Laboratories

1.01.f.1. A special function or other affiliated clinical laboratory that desires to be CAP accredited and is not located in the same building or campus as the main laboratory must have its own CLIA and CAP numbers, unless the main laboratory and affiliated laboratory are granted a multiple-site exemption by the Centers for Medicare and Medicaid Services.

1.01.f.2. A special function or other affiliated clinical laboratory that desires to be CAP-accredited and is not located in the same building or campus as the main laboratory and has its own CLIA and CAP numbers may be inspected during the same inspection event as the main laboratory or may be inspected separately.

1.01.g. Centralized Blood Banks

1.01.g.1. The commission considers a centralized blood bank to be a clinical laboratory that provides any of the following services for a region or community: blood donor services, compatibility testing, other immunohematology procedures, molecular testing for blood groups, therapeutic apheresis, and perioperative autotransfusion.

1.01.g.2. To be eligible for accreditation, a centralized blood bank must meet all existing local, state, and federal laws and licensure requirements, including, for a centralized blood bank subject to CLIA regulations, a current CLIA certificate.
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 nonrefundable.

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 made by the Continuous Compliance Committee.

1.03.a.2. CAP-accredited laboratories subject to US regulations must:

1. Participate in either the CAP Proficiency Testing Programs or a CAP-accepted PT program.

2. Authorize release of their PT results for the purpose of monitoring to the CAP accreditation program and appropriate regulatory or oversight agencies in accordance with US law.

3. Provide on a reasonable basis the laboratory’s annual PT results subject to CLIA upon request of any person.

1.03.a.3. CAP-accredited laboratories not subject to US regulations must participate in the CAP Proficiency Testing Programs and authorize release of their PT results to the CAP accreditation program for monitoring.

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, in special circumstances acknowledged by the Continuous Compliance Committee, 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. 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.1. 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. Accredited laboratories subject to US law must authorize release of this information to appropriate regulatory or oversight agencies in accordance with US and state law.

1.03.b.2. If an accredited laboratory refuses to release PT data to the CAP accreditation program or denies authorization of release of PT data to other appropriate regulatory agencies such as CMS, DOD, the VA, appropriate state agencies, or to any individual in accordance with US law, the laboratory will be considered out of compliance with PT requirements, and the Accreditation Committee may impose sanctions on the laboratory that may include revocation of accreditation.

1.03.c.1. When an accredited laboratory demonstrates unsuccessful* 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 PT performance is unsatisfactory performance in two consecutive testing events or two out of three testing 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 advice on the technical content of the checklists from CAP resource committees and designated work groups.

1.04.b. Checklists are used to evaluate a laboratory’s compliance with the governing Standards for Accreditation. Failure to comply with checklist requirements can constitute independent grounds for imposition of sanctions against a laboratory where the Accreditation Committee concludes that such failure demonstrates unacceptable performance or a threat to the well-being of patients or laboratory personnel.

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.1.2. 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 30 days following an on-site inspection. For phase II deficiencies, acceptable 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. Any such statement must be signed by the laboratory director and accompanied by supporting documentation. A challenge 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 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), accreditation with requirements (1.09), or preliminary accreditation (1.25), ii) be placed on probation with or without immediate jeopardy and/or suspension of accreditation (1.21); or iii) have accreditation 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, the Complaints and Investigations Committee, or the 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, either the committee or the 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, a discussion with the team leader or team member after the inspection, review of the documentation provided in response to deficiencies cited at the time of inspection, or the outcome of a complaint investigation conducted concurrently with the inspection and post-inspection review processes.
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 within 10 to 30 days following the date of the written notification, at the discretion of the Accreditation Committee, the Complaints and Investigations Committee, or the reviewing commissioner.

1.07.e. The Accreditation Committee or the reviewing commissioner may grant a reasonable extension of the period allowed for correction of deficiencies.

1.08 Revocation or Denial of Accreditation

1.08.a.1. The Accreditation Committee 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’s 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, and may also be notified by email. The notice shall include a brief description of the reasons for the denial or revocation.

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 30 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 upon reconsideration, a laboratory whose accreditation has been denied or revoked by the Accreditation Committee 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).

1.08.b.3. The council shall consider a properly filed appeal within 30 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. The notification shall include a short description of the reasons for the determination.

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.a. The Accreditation Committee may grant accreditation with requirements if any one of the conditions of paragraph 1.09.b is met and if the past conduct and present condition of the laboratory cause the committee to conclude that the laboratory is likely to come into compliance with all applicable Standards of Accreditation, accreditation checklist requirements, and CAP accreditation program policies within a reasonable period of time.

1.09.b. The Accreditation Committee may grant accreditation with requirements if it concludes that the laboratory does not pose a substantial risk of harm to patients or to laboratory personnel and that any one of the following conditions is present:

1. Documentation submitted by the laboratory is insufficient to determine compliance with applicable Standards of Accreditation and to assure sustained compliance.

2. The committee wishes to monitor the laboratory’s progress in correcting one or more deficiencies.

3. The laboratory has temporarily discontinued patient testing and services (subsequent to being granted accreditation).

4. The laboratory has not commenced patient testing (prior to its initial inspection).

1.09.c. In determining whether the requirements have been satisfied, the Accreditation Committee may require the laboratory to undergo and pay for a non-routine inspection (which may be announced or unannounced at the sole discretion of the committee). The committee may also require the laboratory to submit whatever additional documentation and take whatever additional steps the committee deems necessary to determine that the requirements have been satisfied.

1.09.d. The Accreditation Committee shall set a specific period of time by which the laboratory must satisfactorily document its fulfillment of all requirements that the committee has imposed.
1.09.e. If the laboratory fails to satisfy the applicable requirements within the time specified in paragraph 1.09.d, the committee may, in its sole discretion, extend the time period for the laboratory to satisfy the requirements, place the laboratory on probation, revoke accreditation, or take such other action as the committee deems appropriate. In making its decision, the committee shall determine the progress that has been made by the laboratory, how close the laboratory is to complying with the applicable Standards of Accreditation, and the risk of harm to patients and laboratory personnel posed by the failure of the laboratory to satisfy applicable requirements.

1.09.f. A decision to grant accreditation with requirements is not subject to a petition for reconsideration or to any appeal.

1.10 Terms of Accreditation

1.10.a. The accreditation of a laboratory remains valid until the next accreditation decision, unless otherwise specified as provided for in 1.09 Accreditation with Requirements.

1.10.b. A laboratory that is due for re-accreditation remains accredited until the Accreditation Committee has made its decision.

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 nonrenewal 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 on-site inspection, and will not accredit any laboratory that has not paid in full its annual accreditation fee or other accreditation-associated charges (eg, 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, a list of laboratories performing nonwaived testing, as defined by the CLIA regulations, for which the individual currently serves as laboratory director, 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.

1.17 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 noncompliance 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. Except as specified in subparagraph 1.17.b.2, the Commission on Laboratory Accreditation will investigate all complaints about a laboratory that is accredited or seeking accreditation. The laboratory must provide timely written documentation of compliance with the governing Standards for Accreditation and accreditation checklist requirements, and any corrective action.

1.17.b.2. A complaint that involves an individual alleged misdiagnosis or misinterpretation, which, in the judgment of the Complaints and Investigations Committee, is unrelated to the governing Standards for Accreditation or the accreditation checklists of the commission, will not be investigated.

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 regional commissioner and a member of the Complaints and Investigations Committee will determine the outcome of each allegation of the complaint. The possible outcome categories are: substantiated; substantiated (not reportable); not substantiated; not applicable; and inconclusive.

1.17.d.2. If the regional commissioner and the Complaints and Investigations Committee member 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 majority vote of the committee members.
1.17.d.3. Upon the conclusion of the complaint investigation, the LAP Investigations Manager will inform a complainant that the complaint investigation has been completed and of the outcome of the investigation.

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 reconsideration within 30 days following receipt of the complaint notification letter. Any request for reconsideration shall be accompanied by documentation supporting the request.

1.17.f.2. The request for reconsideration will be referred to the full Complaints and Investigations Committee for review. The committee shall make a decision within thirty days of such referral. The outcome shall be decided by a 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 reconsideration, the laboratory’s record will reflect the reconsideration 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 Services (CMS) certification, state licensure, or private organization accreditation requirements, the CAP will notify the respective agency or accrediting organization. Notification shall include the date and fact of withdrawal and, if requested by CMS, 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 governing law. If a laboratory is cited for a deficiency and it can demonstrate to the satisfaction of the Commission on Laboratory Accreditation that compliance would cause the laboratory to violate governing law, 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 policy 1.25, the CAP will not inspect or accredit a laboratory that is not currently (a) performing testing of specimens from human beings or animals or (b)
interpreting data from bioinformatics laboratories.

1.20.b. 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 if the Accreditation Committee, in its sole discretion, concludes that 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.

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 – where the investigation or adverse media attention gives reason to believe that the operations of the laboratory may pose a substantial danger to the health or safety of patients or laboratory staff.

7. The laboratory is located in a geographical region in which circumstances, in the judgment of the commission, pose a serious risk to the safety of inspectors.

1.20.c. 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.d. 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.

1.20.e. Denial of eligibility applies to laboratories seeking initial accreditation and accredited laboratories that are reapplying.

1.21 Accreditation with Probation

1.21.a. General

1.21.a.1. The Accreditation Committee may place a laboratory on probation in accordance with paragraph 1.21.b or probation with immediate jeopardy in accordance with subparagraphs 1.21.c.1 and 1.21.c.2. It may also suspend the accreditation of one or more sections of the laboratory in accordance with subparagraphs 1.21.c.1 and 1.21.c.3.

1.21.a.2. A decision to place a laboratory on probation or on probation with immediate jeopardy, and/or a decision to suspend accreditation of a section of the laboratory will be
promptly reported to the appropriate oversight agencies.

1.21.a.3. As a condition of removing any of the sanctions set forth in this policy, the Accreditation Committee may require the laboratory to undergo, and to pay for, a non-routine inspection (or inspections). Inspections may be announced or unannounced, at the discretion of the Accreditation Committee. The purpose of the inspection is to determine whether the issues that led to the imposition of the sanction have been resolved to the satisfaction of the committee. The committee may also require the laboratory to submit any additional documentation the committee deems necessary to determine whether such issues have been resolved.

1.21.a.4. A decision to remove any of the sanctions set forth in this policy will be promptly reported to the appropriate oversight agencies.

1.21.a.5 A laboratory that has been placed on probation shall be notified of the decision. The notice shall include a brief description of the reasons for the placement on probation.

1.21.b. Probation

1.21.b.1. The Accreditation Committee may place a laboratory on probation if any of the conditions set forth in subparagraph 1.21.b.2 are met and if the past conduct or present condition of the laboratory causes the committee to question whether the laboratory will come into sustained compliance with all applicable Standards for Accreditation, accreditation checklist requirements, and CAP accreditation program policies.

1.21.b.2. In accordance with subparagraph 1.21.b.1, the Accreditation Committee may place a laboratory on probation if it concludes that the laboratory does not pose a substantial risk of harm to patients or to laboratory personnel and that any one of the following conditions is present:

1. Documentation submitted by the laboratory is insufficient to determine compliance with the governing Standards for Accreditation, accreditation checklist requirements, or CAP accreditation program policies – or to satisfy the committee that there is likely to be sustained compliance.

2. The committee wishes to monitor the laboratory’s progress in correcting one or more deficiencies.

3. The laboratory has engaged in conduct contrary to the policies of the CAP accreditation programs but such conduct is not, in the judgment of the committee, sufficient to warrant a more severe sanction.

1.21.b.3. A laboratory that is placed on probation may continue to provide testing and other services unless probation includes suspension of accreditation.

1.21.b.4. A laboratory that is on probation will remain on probation until the Accreditation Committee revokes accreditation or removes the laboratory from probationary status, but the committee must revoke accreditation or remove probationary status no later than one year after its decision to place the laboratory on probation.

1.21.c. Probation with Immediate Jeopardy and/or Suspension of Accreditation.
1.21.c.1. The Accreditation Committee may place a laboratory on probation with immediate jeopardy and/or suspend the accreditation of one or more sections of a laboratory, if documentation does not support compliance with applicable accreditation requirements by the laboratory or a section of the laboratory and when, in the judgment of the committee, the noncompliance with one or more requirements has caused, is causing, or is likely to cause, serious injury or is likely to lead to inappropriate medical care, 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. Immediate jeopardy is synonymous with imminent and serious risk to human health and significant hazard to the public safety.

1.21.c.2. If the Accreditation Committee places a laboratory on probation with immediate jeopardy, it shall promptly notify the laboratory of the specific deficiency or deficiencies at issue. The laboratory must correct the deficiencies and document to the satisfaction of the committee that the deficiencies have been corrected within the five business days after notification of the decision to place the laboratory on probation with immediate jeopardy based on the date of the notification letter (ie, not the date the letter is received by the laboratory). If the laboratory does not do so, the Accreditation Committee may revoke the accreditation of the laboratory.

1.21.c.2.b. The Accreditation Committee will report placement of a laboratory on probation with immediate jeopardy to the Centers for Medicare and Medicaid Services and/or to other appropriate oversight agencies within 10 calendar days.

1.21.c.3.a. If the accreditation of a laboratory or a section of a laboratory has been suspended, that laboratory or section may not provide testing or services.

1.21.c.3.b. A laboratory or section whose accreditation has been suspended will not be accredited until all the issues that caused the suspension have been corrected to the satisfaction of the Accreditation Committee.

1.21.c.3.c. If a laboratory or section fails to demonstrate to the Accreditation Committee within 45 days after notification of suspension that it is satisfactorily addressing the issues that caused, the accreditation of the laboratory or a section to be suspended, the accreditation of the laboratory may be revoked.

1.21.c.4. Upon review of the documentation submitted by the laboratory and any other information obtained by the Accreditation Committee (whether from a non-routine inspection or otherwise), the committee may determine to remove the immediate jeopardy status and/or suspension of accreditation of the laboratory or section or sections of the laboratory and maintain the laboratory on probation, remove the probation, accredit the laboratory with requirements, revoke the accreditation of the laboratory, or take such other action as the committee deems appropriate.


1.21.d.1. A laboratory may request reconsideration of any of the sanctions set forth in subparagraph 1.21.a.1 within 30 days after notification of the decision to place the laboratory on probation based on the date of the notification letter (ie, not the date the letter is received by the laboratory) by submitting new information or documentation that was available at the time of imposition of the sanction but that was not considered by the Accreditation Committee – or by explaining in detail why the laboratory believes that the information before the committee at the time of its decision does not warrant the sanction that was imposed.
1.21.d.2. In connection with any request for reconsideration, the laboratory shall indicate whether it wishes to make an oral presentation to the Accreditation Committee.

1.21.d.3. The Accreditation Committee shall determine, in its sole discretion, whether to consider a request for reconsideration exclusively on the basis of written materials submitted by the laboratory, in conjunction with a telephone presentation by the laboratory, or at an in-person presentation by the laboratory. Any costs of the laboratory in connection with a request for reconsideration and/or a presentation shall be borne exclusively by the laboratory.

1.21.d.4. A request for reconsideration shall not stay the effective date of any sanction and shall not operate to prevent notification of the appropriate oversight agencies pursuant to subparagraph 1.21.a.2.

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 have sought 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.1. When there is an urgent need for an accreditation decision prior to the fulfillment of all requirements for full accreditation of a laboratory currently performing testing, the CAP will conduct a routine inspection of the laboratory’s facilities, policies and procedures.

1.25.a.2. Pursuant to paragraph 1.25.b, if the laboratory appears to be in compliance with applicable requirements, it will be granted preliminary accreditation.

1.25.b. The reviewing commissioner may recommend preliminary accreditation prior to accreditation if the findings as reviewed by the CAP accreditation program technical specialist are deemed not to pose a substantial risk of harm to patients and/or to laboratory personnel and both of the following conditions are present:
   1. The Part A general questions have been answered in a manner satisfactory to the reviewing commissioner.
   2. Deficiencies appear to the reviewing commissioner to be resolvable within a 30-day time period.

1.25.c. Subsequent to being granted preliminary accreditation, the laboratory must meet the requirements set forth in policy 1.07 Correction of Deficiencies.

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, QC 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, when the laboratory fails to comply with the policies and procedures of the CAP accreditation programs, or when the laboratory is located in a geographical region in which circumstances arise, subsequent to the laboratory submitting its application for accreditation that, in the judgment of the commission, pose a serious risk to the safety of inspectors. 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) certification, 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 certification 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 seeking reconsideration must submit documents supporting its position, preferably electronically. Furthermore, the director of such 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 upon reconsideration, a laboratory whose eligibility for accreditation 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 eligibility for accreditation.

1.27.d.8. If the denial of 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 reapply after it has first fully addressed all of the issues that resulted in the denial action.

1.27.f.1. A laboratory whose eligibility for accreditation 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.

1.29 **Accreditation Programs Firewall for CAP-approved Proficiency Testing Providers’ Data and Information**

1.29.a. Background. In addition to accepting the CAP’s proficiency testing (PT) programs, the CAP’s Accreditation Program accepts outside PT programs that meet established criteria for analytes identified by the Commission on Laboratory Accreditation (CLA) as requiring enrollment in a CAP-accepted PT program (ie, required analytes). Because of this unique business model, it is critical that certain data and information received by the CAP accreditation staff from external alternate PT programs remain confidential and is not shared beyond the accreditation program. The following describes alternate PT provider data/information that cannot be shared outside of the CAP’s accreditation program to prevent any real or perceived breach of conflict of interest and/or confidentiality. This policy covers information that can be
shared within the CAP and how CAP staff and the Continuous Compliance Committee (CCC) of the CLA can engage members of the CAP’s scientific resource committees for expert opinion on a variety of scientific issues.

1.29.b. CAP accreditation staff and CLA members cannot share:

1. Specific information regarding an alternate PT program that is not otherwise accessible by other means such as a public website or marketing materials.

2. Specific PT program information gathered confidentially during onsite or desk review audits.

3. Individual names of laboratories utilizing alternate PT programs and specific products ordered by a laboratory.

4. Performance data from alternate PT programs either at the laboratory or at the aggregate level.

1.29.c. CAP accreditation staff and CLA members can share:

1. The number of CAP-accredited laboratories that have a specific activity on their activity menu both at the aggregate and individual level.

2. Information on a laboratory’s activity menu.

1.29.d. The CCC and CAP accreditation staff can engage the scientific resource committees of the Council on Scientific Affairs (CSA) and staff of the CAP’s biostatistics department to:

1. Provide input on the clinical validity/importance of proposed new analytes.

2. Provide input on grading schemes for selected analytes.

3. Provide input on educational tools.

4. Provide input on appropriateness of a laboratory’s corrective action for a PT failure.

5. If a PT provider has concerns regarding a decision related to acceptance of an analyte or recommendations on grading schemes, the PT provider can appeal the decision to the CCC and/or the CLA in writing.

1.29.e. A CCC member may hold dual membership on a CSA committee provided:

1. The individual discloses any CSA committee appointments annually as part of the CAP’s Conflict of Interest process.

2. The individual discloses any actual or potential conflict of interest relevant to CCC duties, including any oversight of CAP PT activities.

3. The chair or other presiding official determines that participation in the CSA committee poses no conflict or the conflict is resolvable.
4. The individual is excused from a discussion or decision, or abstains from voting on an issue if there is a perceived conflict of interest.

5. The individual does not participate in the on-site audit of an alternate PT provider.

1.30 Deficiencies

1.30.a. The checklists identify requirements for accreditation to be reviewed during an inspection. Checklist requirements reflect regulatory mandates, good practices in pathology and laboratory medicine, and additional considerations for the health and safety of patients, clients, and personnel.

1.30.b. Failure to comply with a phase II requirement may have a serious impact on the quality of service or may endanger the health and safety of patients, clients, or personnel.

1.30.b.1. Documentation of compliance must be presented for each phase II requirement either on site at the time of an inspection or in response to a citation.

1.30.c. Failure to comply with a phase I requirement will compromise the quality of service without endangering the health and safety of patients, clients, or personnel.

1.30.c.1. The laboratory must comply with each phase I requirement. Submission of documentation of compliance is not required in response to a citation.

1.30.d. A phase 0 item may be included in the checklists for administrative purposes. It is not a requirement.

1.31 Use of the Name and Logo of the CAP by Laboratories

1.31.a. Promotional materials of a laboratory that is accredited by the CAP may include the statement, “This laboratory/biorepository [whichever is applicable] is accredited by the College of American Pathologists,” or any slight variant of this statement. If only certain laboratories within an institution or corporation are accredited by the CAP, such materials must specify the specific sites which are accredited.

1.31.b. A report issued by a laboratory that is accredited by the CAP may include the laboratory’s CAP accreditation number in the form “CAP Accreditation Number XXXXXX.” No other CAP identifier may be used for this purpose.

1.31.c.1. A laboratory accredited by the CAP may not use the CAP’s name or initials except as specified in this policy. A laboratory seeking accreditation may not use the CAP’s name or initials in any manner.

1.31.c.2. A laboratory accredited by the CAP or a laboratory seeking accreditation may not use the logo of the CAP in any manner.

1.31.d. A laboratory that is accredited by the CAP and is using the name or initials of the CAP in accordance with this policy must immediately cease use of such name or initials if the laboratory withdraws from the CAP’s accreditation programs or loses its accreditation.
1.31.e. The CAP reserves the right to withdraw the accreditation of, or take legal action against, any laboratory that uses the CAP’s name, initials, or logo in violation of this policy. Any question about whether a proposed use of the CAP’s name or initials comports with this policy should be addressed to the director, Accreditation and Regulatory Affairs, at the CAP.

1.31.f. Promotional materials of the laboratory that is accredited by the CAP may use the CAP Certification Mark in accordance with the CAP Certification Mark Usage Guidelines. Laboratories seeking accreditation may not use the CAP Certification Mark.

1.31.g. A laboratory accredited by the CAP that uses or intends to use the CAP Certification Mark must accept and adhere to the Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design.

1.32 Use by an Accredited Laboratory of the CAP Number on Reports Containing Results from Tests outside the CAP’s Areas of Medical Expertise

1.32. A laboratory that is accredited by the CAP shall not include its CAP number or any other reference to the CAP on any reports, or promotional materials, that make reference to tests or biorepository services outside the CAP’s areas of medical expertise. If a laboratory has questions about whether a test or service is within the area of the CAP’s expertise, it should contact the director of Accreditation and Regulatory Affairs at the CAP.

1.33 Laboratory Directorship Limit

1.33. A laboratory director must direct no more than five laboratories that perform nonwaived testing, as defined by the CLIA regulations. This limitation shall apply to laboratory directors of all CAP-accredited laboratories.

1.34 Continuing Accreditation in the Absence of an Onsite Inspection

1.34.a.1. If the Commission on Laboratory Accreditation requires a CAP-accredited laboratory to undergo a self-inspection in lieu of a routine on-site inspection due to circumstances in the geographic region where the laboratory is located that, in the judgment of the commission, pose a serious risk to the safety of the inspector(s), the laboratory shall comply with the following requirements:

1.34.a.2. A laboratory required to undergo a self-inspection in lieu of a routine inspection pursuant to section 1.34.a.1 must:

1. Submit notification of the completion of the self-inspection prior to the laboratory’s anniversary date.

2. Submit with such notification a list of all deficiencies noted during the self-inspection.

3. Submit documentation of corrective action for all deficiencies noted.

4. Submit documentation demonstrating continued compliance with any additional requirements imposed by the Accreditation Committee and corresponding to deficiencies identified at the laboratory’s previous inspection.
5. Submit a copy of its quality management plan, quality control indicators, maintenance records, validation documentation of new instruments, and lot-to-lot reagent and inter-instrument comparisons from the previous two years.

6. Submit to an on-site inspection after the circumstances that led to the requirement of a self-inspection in lieu of an on-site inspection have improved to the point that, in the judgment of the commission, there is no longer a serious risk to the safety of the inspector(s).

7. Enroll and participate in all required proficiency testing pursuant to policy 1.03 Participation in Proficiency Testing.

8. Comply with all accreditation program standards, accreditation checklist requirements, and policies.

1.34.b. A laboratory required to undergo a self-inspection in lieu of an on-site inspection must submit all documentation required by 1.34.2 within 30 days following the date of the commission’s written notification that a self-inspection will be required.

1.35 Post-inspection Review and Accreditation Decision in the Absence of an Onsite Inspection

1.35.a. When a laboratory that is required to undergo a self-inspection in lieu of an onsite inspection submits all required documentation pursuant to section 1.34.a.2, the CAP shall record all deficiencies noted by the laboratory during the self-inspection as part of the routine inspection cycle.

1.35.b.1. The technical specialist and the reviewing commissioner will review the documentation of corrective action for all deficiencies cited, pursuant to policy 1.07 Correction of Deficiencies, and all other documentation submitted by the laboratory to ensure that the laboratory meets the governing Standards for Accreditation and applicable accreditation checklist requirements. The Accreditation Committee will make an accreditation decision based on such review.

1.35.b.2. If the committee accredits the laboratory, the laboratory will be granted accreditation with the requirement of an on-site inspection and any additional requirements the committee deems appropriate pursuant to policy 1.09 Accreditation with Requirements.

1.35.c.1. The Accreditation Committee may require a laboratory that cannot undergo a routine inspection due to circumstances that pose a serious risk to the safety of the inspector(s) for more than one onsite inspection cycle to withdraw from the accreditation program.

1.35.c.2. A laboratory that has been required to withdraw from the accreditation program may reapply for accreditation after the circumstances that led to the requirement of a self-inspection in lieu of an onsite inspection have improved and the commission has determined that its inspectors may safely perform an onsite inspection.

1.35.c.3. A laboratory that chooses to reapply for accreditation will be assessed fees equal to those fees assessed for a new application.
1.36 Accreditation of Laboratories Not Performing Testing

1.36.a. Laboratories that temporarily suspend operations.

1.36.a.1. The Accreditation Committee may change the accreditation status of a CAP-accredited laboratory to accreditation with requirements, pursuant to policy 1.09 Accreditation with Requirements, if the laboratory has temporarily discontinued patient testing and services but successfully continues to participate in proficiency testing enrollment and reporting, and also complies with other accreditation requirements set forth by the committee.

1.36.a.2. The laboratory must notify the CAP that it has temporarily discontinued patient testing and services within 30 days from the date that the laboratory suspended operations.

1.36.a.3. Except as indicated in 1.36.a.4, if the laboratory has not recommenced patient testing within three months after ceasing operations, the Accreditation Committee may revoke the accreditation of the laboratory.

1.36.a.4. A laboratory that has suspended operations due to a disaster or a laboratory not subject to the CLIA regulations that has temporarily discontinued testing may be granted accreditation with requirements for up to one year, after which time the Accreditation Committee will reconsider the laboratory’s accreditation status at its next meeting.

1.36.b. Laboratories that seek accreditation prior to the commencement of patient testing.

1.36.b.1. Except for cases in which accreditation is required by law before patient testing can commence, the Commission on Laboratory Accreditation will determine at its sole discretion whether it shall inspect a laboratory prior to the commencement of patient testing by the laboratory.

1.36.b.2. When a laboratory applying for CAP accreditation requests to be inspected before patient testing has commenced (Florida initial laboratories, clinical drug trial laboratories, etc), the CAP will conduct an inspection of the laboratory’s facilities, policies, and procedures.

1.36.b.3. If the laboratory appears to be in compliance with applicable accreditation checklist requirements it will be granted accreditation with requirements, pursuant to policy 1.09, and such accreditation will include the following requirements:

1. The laboratory must commence patient testing within three months from the date that the accreditation with requirements was granted.

2. The laboratory must notify the CAP that it has commenced testing within 30 days from the date that it initiated patient testing.

3. Except as indicated in 1.36.b.5, the laboratory must undergo a complete inspection within three months after patient testing commences.

1.36.b.4. The laboratory will be charged additional fees for any subsequent inspection.
1.36.b.5. International laboratories not subject to the CLIA regulations may undergo a complete inspection that occurs beyond the three-month timeframe after testing commences so that the inspection may occur at the time of the next CAP inspection of another laboratory in the region.

1.36.b.6. If the laboratory has not commenced patient testing within three months from the date that it was granted accreditation with requirements, the Accreditation Committee may revoke the accreditation of the laboratory.

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's accreditation programs. To that end, the following prohibitions apply:

2.01.a.1. No inspector may have a close personal, family, business or professional relationship with any person overseeing or working in a laboratory or its parent institution or associated entity that they inspect.

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 noncash gifts, including products, services, or entertainment provided at no cost or a 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 regional commissioner any facts or relationships that are inconsistent with the above prohibitions, and any other potential conflicts of interest.

2.01.b.2. The prohibitions of paragraph 2.01.a.3 shall apply throughout the course of the inspection and for 75 days after the date of the inspection.

2.01.b.3. Violation of one of the above prohibitions by an inspector does not necessarily taint the fairness of the inspection as a whole or of the accreditation decision.

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
2.02 Size and Composition of the 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 clinical biochemical genetics, 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. A non-routine inspection is an on-site inspection that is performed at any time other than the three-month window prior to the laboratory's anniversary date.

2.03.b.1. The Commission on Laboratory Accreditation, the Accreditation Committee, the Complaints and Investigations Committee, the Continuous Compliance Committee, or the reviewing commissioner in consultation with the chair of the Commission on Laboratory Accreditation (or his/her designee), 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.

2.03.b.2. 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.

2.03.b.3. The inspection may be announced or unannounced.

2.03.c. Non-routine inspection, Added Discipline.

2.03.c.1. A non-routine inspection may be required by the Accreditation Committee or by the reviewing commissioner when a laboratory adds a discipline or disciplines other than histocompatibility.
2.03.c.2. A non-routine inspection will be required when a laboratory adds histocompatibility.

2.03.d. Non-routine Inspection, Allegation of Noncompliance.

2.03.d.1. A non-routine inspection may be required if there is an allegation, or other reason to believe, that the laboratory is out of compliance with accreditation checklist requirements or the governing Standards for Accreditation, regardless of the source of that information.

2.03.d.2. A non-routine inspection conducted on a laboratory subject to CLIA regulations due to an allegation of noncompliance must be unannounced.

2.03.e. Following the non-routine inspection, the inspected laboratory must comply with the requirements of policy 1.07 Correction of Deficiencies.

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 return their completed interim self-inspection attestation page to the CAP within 60 calendar days of receipt.

2.04.e. Failure to promptly notify the CAP accreditation programs that the interim self-inspection has been completed may result in an adverse action against the laboratory’s accreditation status.

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 a laboratory to be inspected has reason to believe that a 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 ensure an appropriately objective accreditation decision.

2.07 Use of Checklists

2.07.a. All routine inspections and self-inspections must be conducted using a Laboratory General Checklist, one discipline-specific checklist for each discipline in which a laboratory offers patient testing per section unit and one All Common Checklist for each section unit.

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 must not be in a business, professional or personal relationship that would preclude an objective inspection of the assigned laboratory.

2.08.b. For routine domestic inspections, 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. Under exceptional circumstances, the chair of the Commission on Laboratory Accreditation may grant an exception.

2.08.c. For routine domestic inspections, 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. Under exceptional circumstances, the chair of the commission may grant an exception.

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. Inspections for the Reproductive Laboratory Accreditation Program, Forensic Drug Testing Accreditation Program, and Biorepository Accreditation Program should occur within the 90 days prior to the anniversary date and will be announced.

2.10.d. The Commission on Laboratory Accreditation may require a CAP-accredited laboratory to undergo a self-inspection in lieu of a routine onsite inspection, pursuant to policy 1.34 Continuing Accreditation in the Absence of an Onsite Inspection, due to circumstances in the geographical region where the laboratory is located that, in the judgment of the commission, pose a serious risk to the safety of the inspector(s).

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 or when the accreditation of the institution is denied or revoked. The “Do Not Use” status 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 and Investigations Committee, Commission on Laboratory Accreditation, or Council on Accreditation.

2.11.b. An individual who has performed contrary to 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 status may include, but is 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.

2.12 Limited Service Testing

2.12.a. A section of a laboratory may be designated a limited service testing site; this designation would allow the section to be inspected with the Limited Service Checklist.

2.12.b. For a section to qualify as a limited service testing site, it must meet the following criteria:

1. Perform fewer than 100 activities.

2. Perform testing under one section/department supervisor.

3. Perform testing in two or more of the following disciplines or activities:
   - Chemistry
   - Hematology
   - Immunology
• Microbiology
• Urinalysis
• Blood typing or screening (nontransfusion)

4. Perform routine testing of a basic complexity, as determined by the Commission on Laboratory Accreditation.

2.12.c.1. Each section of a laboratory that is designated a limited service testing site will be inspected with its own Limited Service Checklist and All Common Checklist.

2.12.c.2. If all the testing within a laboratory in aggregate meets the criteria set forth in paragraph 2.12.a, the entire laboratory shall be inspected as a single section with a single Limited Service Checklist along with the Laboratory General Checklist, the Team Leader Assessment of Director and Quality Checklist, and the All Common Checklist.

3. INSPECTORS

3.01 Reimbursement of Travel Expenses for CAP Inspections

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 by the appropriate CAP accreditation programs professional staff director.

3.01.d. Special ground transportation (limousines, vans, shuttles, buses, etc.) must be approved in advance by the appropriate CAP accreditation programs professional staff director.

3.01.e. The chair of the Commission on Laboratory Accreditation or designee must review and approve (or deny) unusual requests for reimbursement.

3.02 Inspection Team Leaders, Inspection Team Members, 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 appropriate knowledge and experience or have had their credentials verified and approved by the appropriate resource committee or the commission should be included as the team leader or 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.c.4. Whenever a coordinated AABB/CAP inspection is requested and approved, the AABB will assign an assessor to perform the inspection of the transfusion service for both entities. For multi-discipline laboratories, the AABB assessor is considered a team member of the CAP inspection team regardless of whether or not the inspection occurs simultaneously with the CAP inspection of the rest of the laboratory. The AABB assessor’s scope of responsibility is limited to the transfusion medicine discipline, the All Common Checklist, and the portions of the Laboratory General Checklist pertaining to safety, personnel, and the appropriate laboratory information systems requirements for the transfusion service. Inspection of other disciplines requires prior approval by CAP. If the laboratory has no other disciplines beyond transfusion medicine, the assigning commissioner may approve the AABB assessor to act as the team leader and perform the full inspection.

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. International Inspectors. Team leaders will be required to include appropriately qualified and trained 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 the required training 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 mastery (eg, by passing a competency assessment) 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 demonstrate proficiency by receiving generally positive inspection feedback and must complete any additional training specified by the commission.

3.03.b.1. Inspection team members must successfully complete the required training prior to conducting an inspection.

3.03.b.2. All team members must successfully complete team member initial training and demonstrate mastery (eg, by passing a competency assessment) 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 receiving generally positive feedback and must complete additional training specified by the commission.

3.03.c.1. Inspectors based outside of the US must successfully complete training and maintain competency as a team leader or team member, as appropriate, as noted in sections 3.03.a and 3.03.b above. The international inspector should be currently or previously affiliated with a CAP-accredited laboratory. Inspection techniques should be assessed by an experienced inspection mentor during the initial inspection.

**3.04 International Inspection Travel and Assignments**

3.04.a.1. All inspectors originating in the US may travel business class for all portions of flights to countries outside of North America.

3.04.a.2. All inspectors originating in the US must travel economy class for all portions of flights within the United States and within the country traveled to for inspection.

3.04.b. All inspectors originating outside of the US may travel business class for all portions of flights for which the total flight time exceeds five hours (excluding layovers). For flights of five hours or less, such inspectors must travel economy class.

3.04.c. For international region (non-US) inspections, regional team member assignments will be made from the same country or from a country within the closest proximity to the laboratory being inspected. Exceptions may be made with the approval of the chair of the Council on Accreditation, the chair of the Commission on Laboratory Accreditation, or the CAP vice president for the Laboratory Improvement Programs. Requests for exceptions should be submitted as early as possible so that the inspector assignment is not impacted if the request is not granted.
3.04.d. All inspectors inspecting international Department of Defense contract laboratories must travel economy class (per the Department of Defense contract with CAP). The CAP Travel Desk will book premium upgradable economy class airfare. This allows those inspectors who choose to personally upgrade their tickets to do so.
Let Them Know You’ve Earned the Mark

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

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

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

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
800-323-4040
847-832-7000