Dear Laboratory Colleague,

The *Laboratory Accreditation Overview* is your comprehensive resource for exploring the benefits of Joint Commission Laboratory Accreditation and key information regarding our process including:

- The initial application process
- Types of surveys and laboratories accredited
- Survey agenda
- Intracycle Monitoring (ICM)
- Tracer Methodology
- Lab Central Connect

This overview is focused primarily towards “initial” or first-time applicants to the Joint Commission accreditation process but is also relevant to laboratories seeking continued accreditation with us.

I look forward to answering your questions or discussing in detail how Joint Commission accreditation can help your lab achieve its quality and safety goals. Please don’t hesitate to contact me directly at the phone or email information below.

Thank you again for your interest in the Joint Commission’s Laboratory Accreditation Program.

Sincere regards,

Jennifer Rhamy, MBA, MA, MT(ASCP) SBB, HP
Executive Director
Laboratory Accreditation Program
630.792.5754, jrhamy@jointcommission.org
Directory of Laboratory Accreditation Resources

Seeking Joint Commission Accreditation

For information on accreditation, questions or comments on the Laboratory Accreditation Program:
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(630)792-5754
jrhamy@jointcommission.org

For questions on applying for Joint Commission accreditation for the first time or to request an Application for Accreditation:
Sharon Hibbe, Project Manager-Business Intelligence
(630)792-5817
shibbe@jointcommission.org

Proficiency Testing

For questions about unsuccessful proficiency testing and corrective plans of action:
Eileen Stawczyk, MT (ASCP), Project Manager
(630)792-5248
estawczyk@jointcommission.org

Standards Interpretation Group

For information regarding interpreting and applying specific standards:
(630)792-5900 Option 6

For information about interpreting and applying specific laboratory standards, request assistance from a laboratory specialist:

An online standards questionnaire form is also available at:
http://www.jointcommission.org/standards_information/standards_online_question_form.aspx

For “Frequently Asked Questions about Standards” go to:
http://www.jointcommission.org/standards_information/jcfaq.aspx

For information and “Frequently Asked Questions about the National Patient Safety Goals (NPSGs)” go to:
http://www.jointcommission.org/standards_information/npsgs.aspx

For “Frequently Asked Questions about Laboratory Accreditation”:
http://www.jointcommission.org/accreditation/laboratory_seeking_accreditation.aspx
Pricing

For questions on survey fees and application deposits:
Planning and Financial Affairs
(630)792-5115

Current Customers
Accredited organization may contact their assigned Account Executive at his/her extension or (630)792-3007

Joint Commission
Web Site: [www.jointcommission.org](http://www.jointcommission.org)
- Standards Information and FAQs
- Proficiency Testing
- News and Articles
- Educational Resources

Joint Commission Resources
Web Site: [www.jcrinc.com](http://www.jcrinc.com) or (877) 223-6866
- To purchase a standards manual
- To register for, or receive information about education programs, and to purchase, or inquire about publications
- Catalog of publications
- Perspectives: The Official Joint Commission News Source
# Excellence in Laboratory Accreditation

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Why Choose Joint Commission Laboratory Accreditation?

We accredit more organizations than anyone else in health care
The Joint Commission accredits over 20,000 health care organizations, including approximately 1700 clinical laboratories holding close to 2,500 certificates. The Joint Commission is the leader in accreditation, with nearly 60 years of experience across the full spectrum of health care organizations. Joint Commission accreditation, which is awarded to a laboratory every two years, represents the “Gold Seal of Approval” in health care and provides the most comprehensive evaluation process in the industry.

The Joint Commission Laboratory Accreditation certificate demonstrates to patients and their families that the laboratory has a commitment to providing safe, quality care and services for patients integrated with the entire organization. As the demand for greater accountability for quality and cost grows, it is more important than ever to have the quality distinction that is part of the facility’s overall quality management systems. Achieving accreditation makes a strong statement to the community about a laboratory’s efforts to provide patient safety and services of the highest quality.

CLIA certification
The Joint Commission began evaluating laboratory services separately in 1979 and has deeming authority under the Clinical Laboratory Improvement Amendments (CLIA) for CMS. Many states recognize the Joint Commission’s accreditation process in lieu of their own, saving you a redundant inspection.

All labs in organization surveyed concurrently
A key advantage of the laboratory survey process is that all laboratories within an organization can be reviewed during the course of one survey. For example, freestanding ambulatory care centers, surgery centers, behavioral health and long term care facilities, as well as hospitals, are often part of the same health care organization. Many have their own laboratory services, each with a CLIA certificate number. The Joint Commission survey covers not only laboratories in the hospital, but also laboratories serving different organizational elements even if services are provided off-campus or in a neighboring state. A separate survey request for each laboratory is not required which can save you both time and money. In addition, you are guaranteed of a consistent team looking at all of your processes.

Other key advantages of the Joint Commission’s accreditation process
➢ Focuses on analysis processes and patient outcomes rather than just compliance with technical requirements.
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- Tracers assess the effectiveness of patient care processes in meeting high standards of quality and safety by following laboratory results all the way to the patient’s chart.

- **NO** reciprocal surveys to perform. **NO** inspection training to attend. **NO** large numbers of laboratory staff showing up to inspect, and potentially disrupt services in your lab.

- Dedicated account executive ensures you reach the correct resource at The Joint Commission.

- Professional, employed surveyors. Each surveyor surveys from 45 – 70 labs per year, so therefore they are better able to share leading practices seen in other labs. This adds consistency to the survey process and prevents possible institutional bias.

- Each laboratory is provided a secure log in on The Joint Commission Connect extranet site to receive and submit all Joint Commission information.

- Smaller surveyor teams for more days can be less disruptive to larger labs and provides opportunities to show full process outcomes rather than one day’s output.

- A non-punitive Intracycle Monitoring (ICM), which is a self-assessment for identifying opportunities for improvement and supporting continuous standards compliance. Includes the option for a phone conference with Joint Commission staff, who can assist you with and approve your Plans of Action.

- Year-round access to laboratory professionals in the Standards Interpretation Group via phone and online support for your standards related questions.

- Complimentary membership in the Lab Advantage Program which is a collaboration between The Joint Commission, American Society for Clinical Pathology and the American Proficiency Institute. The Lab Advantage Program achieves significant cost reductions in proficiency testing, staff education, and accreditation fees.

- Reduces redundancy resulting from managing multiple accreditation organizations. The Joint Commission is also recognized by many states as satisfying the need for a state CLIA survey.

- Assists senior leadership in better recognizing how the hospital or facility and laboratory must align to assure overall quality and safety of patient care due to the high organizational visibility of the survey.
INITIAL APPLICATION PROCESS

What types of laboratories can become Joint Commission accredited and what are the eligibility requirements?
The Joint Commission surveys many different types of clinical laboratories:

- Hospital laboratories
- Reference laboratories
- Physician office laboratories
- Assisted reproductive technology laboratories
- Clinics
- Long term care facilities
- Home care organizations
- Behavioral health organizations
- Public health laboratories, including Indian health services
- Ambulatory sites
- Blood transfusion
- Federally owned laboratories.

For purposes of CLIA certification, laboratory testing is defined as analyzing a substance removed from the body and using this information for the diagnosis, prevention, or treatment of any disease, impairment, or assessment of the health of human beings.

CLIA regulations require that laboratory surveys be conducted every two years. This means that, if your laboratory is part of another Joint Commission accredited health care organization, your survey may not ordinarily take place at the same time as your health care organization’s triennial survey.

Any health care organization may apply for Joint Commission laboratory accreditation if all the following requirements are met:

- The laboratory is in the United States or its territories or, if outside the United States, is operated by the U.S. government, or under a charter of the U.S. Congress.
- The laboratory assesses and improves the quality of its services. This process includes a review of care by clinicians, when appropriate.
- The laboratory identifies the services it provides, indicating which services it provides directly, under contract, or through some other arrangement.
- The laboratory provides services addressed by The Joint Commission’s standards.

For laboratories with a new CLIA number and Laboratory Registration Certificate, Federal Requirements require accreditation be obtained within 11 months of issuance of the certificate. Ideally, the laboratory should apply for accreditation and indicate a preferred survey month in the Application for Accreditation no earlier than three months after issuance to ensure the track record is established by the time of the initial survey.
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and no later than eight months (seven months preferred) after issuance to accommodate the 30 day advanced notification for survey and completion of the accreditation process.

Laboratories issued a Laboratory Registration Certificate should note the following Federal Register Laboratory Requirement 493.57 (b)(1)(i) when specifying the preferred month of survey in the Application for Accreditation. The laboratory must provide Health and Human Services (HHS) with proof of accreditation within 11 months of issuance of the registration certificate

Types of Testing
Laboratory testing is divided into three categories by CLIA. The final rules of CLIA enacted in April 2003 combine many requirements for moderate and high complexity and refer to them as “non-waived”:

- **waived tests** – simple procedures with little chance of negative outcomes if performed inaccurately.

- **non-waived tests:**
  - moderately complex tests – more complex than waived testing but usually automated, such as blood counts. This includes PPMP, which are tests being performed by a qualified provider, for example KOH preps
  - highly complex tests – usually non-automated or complicated tests requiring considerable judgment, such as cross matching of blood.

For all non-waived tests, CLIA requires an on-site survey or accreditation by an approved agency, such as The Joint Commission. In addition, hospital accreditation surveys will evaluate the quality of waived testing even if it is not covered by your laboratory accrediting body. With the Joint Commission laboratory accreditation, you can have this testing evaluated by laboratorians who can consult with the hospital staff about the best practices.

Applying for the first time
A laboratory that is seeking Joint Commission accreditation for the first time or that has not been unaccredited by The Joint Commission during the previous 6 months is eligible for an initial survey. The full scope of applicable standards is reviewed during the survey. The evaluation of the standards is based on a 4-month track record of compliance (prior to the survey) rather than the 24-month track record of compliance required for re-surveys. If a laboratory is seeking Joint Commission accreditation for the first time, but has been accredited by another laboratory accrediting organization up until that time, it must demonstrate not only a 4-month track record of compliance with Joint Commission standards but must also demonstrate a 24-month track record of proficiency testing.
How do I apply for an initial laboratory survey?
Organizations that wish to be accredited by The Joint Commission should ask for an Application for Initial (or first time) Laboratory Accreditation by contacting Sharon Hibbe, Project Manager – Business Intelligence, at (630) 792-5817 or shibbe@jointcommission.org. If you need more information in preparation for obtaining an application, please contact Jennifer Rhamy, Executive Director, at jrhamy@jointcommission.org.

• The application for Initial Laboratory Accreditation is valid for twelve months from the date submitted, which means you can submit your application and still have time to finish your preparations before the on-site survey takes place.

• For new laboratories, obtain your CLIA number prior to applying for Joint Commission accreditation and at any time within the four months before you plan to initiate testing.

• It is best to submit your application when you are confident you will be able to demonstrate a four-month track record of compliance at the time of the on-site survey.

• Take note of timelines and coordinate the accreditation application with your account executive accordingly.
  o For new laboratories with a new CLIA number, accreditation must be obtained within 11 months of issuance. Ideally, the laboratory should apply for accreditation no earlier than three months after issuance to ensure the track record is established by the time of the initial survey, and no later than eight months after issuance to accommodate completion of the accreditation process.
  o For existing laboratories converting their accreditation to The Joint Commission, accreditation may be obtained anytime in the two-year accreditation cycle. If you are planning to convert when your current accreditation expires, application to The Joint Commission is ideally made at least four months prior to the expiration to accommodate completion of the Joint Commission’s accreditation process.
  o Other timeframes may be accommodated by discussing with your account executive.

• For initial surveys, the application is submitted with a nonrefundable deposit, which is applied to your accreditation fee. Call (630) 792-5665 to submit your application deposit by credit card or to obtain the mailing address to submit a payment by check.

• On your application for Initial Laboratory Accreditation, specify time periods when you would like the survey to take place (the initial survey is announced), and/or
specific time periods when you would prefer the survey not to take place. The Joint Commission will make every effort to accommodate your request. The earlier you submit your request, the more likely it is that your specific time period can be accommodated.

**What are the next steps after your initial laboratory application is received?**

Once the application for accreditation is received by The Joint Commission, you will be assigned an account executive who will:

- Answer your questions about survey preparation, and help you through each step of the accreditation process
- Analyze your application for accreditation, and contact you if there are any questions or items requiring clarification,
- Update changes to your demographic information, including address, contact name(s), etc.
- Assist you with other Joint Commission contacts and questions.
- Assist you in gaining access to Intracycle Monitoring (ICM) Tool which will help you prepare for your initial survey and is a requirement for laboratories to maintain your accreditation.

The Joint Commission initial laboratory on-site survey is scheduled as an announced survey based on information provided in your application. With the information provided, The Joint Commission determines the number of days required for a survey, the composition of the survey team, the fee, and the services to be reviewed.

Approximately four weeks before the survey, you will be notified of the date(s) of the initial survey. This date will be posted on The Joint Commission Connect secure extranet site. At that time you will be told what documents and records you will need to gather for the survey.

**What are the accreditation requirements for laboratories seeking Joint Commission accreditation?**

A laboratory seeking accreditation from The Joint Commission must demonstrate compliance with the following: standards, National Patient Safety Goals, Accreditation Participation Requirements (APRs), Proficiency Testing (PT), and documentation.

1) **Standards**

The Comprehensive Standards Manual for Laboratories (CAMLAB) is designed for use in self-assessment activities and includes the requirements that form the basis of the accreditation survey. The standards manual is divided into chapters as follows:

- Accreditation Participation Requirements
- Document and Process Control
- Environment of Care
- Emergency Management
- Human Resources
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- Infection, Prevention and Control
- Information Management
- Leadership
- National Patient Safety Goals
- Performance Improvement
- Quality System Assessment for Non-waived testing
- Transplant Safety
- Waived Testing

Each standard is formatted to include:
- The standard itself, which is the “goal.”
- The rationale which explains why it’s important to achieve this goal.
- The elements of performance which identifies the step(s) needed to achieve this goal.

Elements of Performance (EPs) are the portion of the standard that is scored by the surveyor on site. EPs clearly present the requirements that are assessed during the on-site review and will be scored on a three-point scale of “0=insufficient compliance,” “1=partial compliance,” and “2=satisfactory compliance.”

- Category A EPs relate to the presence or absence of the requirement(s), and are scored either yes (2) or no (0).
- Category C EPs are scored based on the number of times an organization does not meet a particular EP.
  - An EP is scored 2 if there are one or fewer occurrences of non-compliance with the EP.
  - It is scored 1 if there are two occurrences of non-compliance with the EP.
  - It is scored 0 if there are three or more occurrences of non-compliance with the EP.

The goal of the C scoring category is to assist in identifying a pattern of performance (or non-performance). If the laboratory feels that the pattern of performance identified by a surveyor(s) is not representative of performance in their lab, they may sample (post survey) and submit their results to The Joint Commission for consideration in rendering a final decision.

Non-compliance with a standard or requirement results in the laboratory being assigned a Requirement for Improvement (RFI). All RFIs must be addressed in the Evidence of Standards Compliance (ESC) process in order for accreditation to be awarded.

2) National Patient Safety Goals
The Joint Commission issues a set of National Patient Safety Goals and requirements each year. Aggregate data on achievement of the Goals will be made public each year. The Goals were developed by an expert advisory group composed of physicians, nurses, risk managers and other professionals. The Goals and related Implementation Expectations were drawn from over 30 issues of the Joint Commission’s patient safety
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newsletter Sentinel Event Alert. New Patient Safety Goals will be announced on an annual basis.

**National Patient Safety Goals for Laboratories**

Goal 1 – Improve the accuracy of patient identification.
- Use of Two Patient Identifiers

Goal 2 – Improve the effectiveness of communication among caregivers.
- Timely Reporting of Critical Results

Goal 7 – Reduce the risk of health care-associated infections.
- Meeting Hand Hygiene Guidelines

For each of the applicable National Patient Safety Goals, The Joint Commission has released evidence-based requirements to help laboratories reduce specific types of errors. Accredited organizations that provide care relevant to the Goals will be evaluated for compliance with the requirements or implementation of acceptable alternatives.

Information about the National Patient Safety Goals can be found on the Joint Commission web site, [http://www.jointcommission.org/standards_information/npsgs.aspx](http://www.jointcommission.org/standards_information/npsgs.aspx)

Other sources of information include Joint Commission Perspectives, and Perspectives on Patient Safety. Subscriptions for both periodicals are available through the Joint Commission Resources web site, [www.jcrinc.com](http://www.jcrinc.com).

**3) Accreditation Participation Requirements**

Additional requirements for participation in the accreditation process and for maintaining an accreditation award are below:

APR.01.01.01: The laboratory submits information to The Joint Commission as required.

APR.01.02.01: The laboratory provides accurate information throughout the accreditation process.

APR.01.03.01: The laboratory reports any changes in the information provided in the application for accreditation and any changes made between surveys.

APR.02.01.01: The laboratory permits the performance of a survey at The Joint Commission's discretion.
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APR.03.01.01: The laboratory fulfills requirements for Intracycle Monitoring (ICM).

APR.05.01.01: The laboratory allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.

APR.06.01.01: Applicant or accredited laboratories do not use Joint Commission employees to provide accreditation-related consulting services.

APR.07.01.01: The laboratory accepts the presence of Joint Commission surveyor management staff or a Board of Commissioners member in the role of observer of an on-site survey.

APR.08.01.01: The laboratory accurately represents its accreditation status and the facilities and services to which Joint Commission accreditation applies.

APR.09.01.01: The laboratory notifies the public it serves about how to contact its laboratory management or The Joint Commission to report concerns about patient safety and quality of care.

APR.09.02.01: Any individual who provides care, treatment, or services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the laboratory.

APR.09.03.01: The laboratory is truthful and accurate when describing information in its Quality Report to the public.

APR.10.03.01: The laboratory complies with the Joint Commission’s requirements addressing unsuccessful proficiency testing. (See Proficiency Testing)

Award of certificate
If a laboratory is in compliance with all standards at the time of the on-site survey, the accreditation decision is rendered at the same time that the laboratory’s Summary of Survey Findings Report is available. It is effective the day after the completion of the survey. If the laboratory is not fully compliant with one or more standards at the time of survey, it is required to submit an acceptable Evidence of Standards Compliance (ESC) Report (See Scoring and Criticality).
If the ESC is acceptable, the laboratory’s accreditation decision is retroactive to the day after the last day of the survey, unless the laboratory is undergoing its first Joint Commission survey. In that case, the effective date is set retroactively as the date on which the acceptable ESC that resolves all requirements for improvement is submitted. The ESC can be submitted directly via the organization’s secure extranet site, *The Joint Commission Connect*.

**What are the fees for lab accreditation?**

For all Joint Commission accreditation programs, a subscription billing package approach involves annual billing at a base rate and the assessment of add-on fees to cover all survey-related direct costs in those years in which on-site surveys are conducted. This annual fee structure aligns with the reality that Joint Commission accreditation-related services are now provided on a continuous basis. For additional information, contact the Pricing Unit at (630) 792-5115.

**Lab Advantage Option**

The Lab Advantage program is a collaborative relationship between The Joint Commission, American Proficiency Institute (API) and the American Society for Clinical Pathology (ASCP). In order to take part, a Joint Commission accredited lab must participate in API proficiency testing. ASCP educational sessions are provided at a 10% discount and The Joint Commission will provide a 5% discount annually on accreditation fees. If interested in participation, please notify Sharon Hibbe, Project Manager – Business Intelligence, at (630) 792-5817 or shibbe@jointcommission.org within 30 days of eligibility.

For more information on how to take advantage of this cost efficient approach to laboratory accreditation, refer to the web site: [http://www.LabAdvantage.com](http://www.LabAdvantage.com) or send an email to info@labadvantage.org.

**Pathologist Specialist Option**

A laboratory may choose to include a pathologist in the survey team that conducts the laboratory’s accreditation survey. This option is available at an additional cost. Please contact the Pricing Unit for the actual cost for your laboratory. The pathologist surveyor provides enhanced expertise and consultation during the survey of performance improvement activities, laboratory directorship activities, and cytology and anatomical pathology activities.

**Multiorganization Option**

The Joint Commission offers a multiorganization system that owns or leases at least two organizations the option of using a modified survey process. This option has the following three components:

1. A corporate orientation held at the beginning of the year

2. Surveys of participating organizations with the same survey team leader
3. A corporate summation after the last organization in the system is surveyed

The orientation session provides an opportunity for corporate staff to orient the survey team to the structure and practices of the system. The corporate summation provides an overall analysis of the system’s strengths and weaknesses. It also provides consultation and education related to accreditation survey findings across the system. Both the orientation and the summation can be conducted via audio conference or onsite. There is a separate fee for the corporate survey option. Please contact your Account Executive for more information.

Continuity in the composition of the survey team is maintained by the survey team leader(s). The remaining members of the survey team rotate in and out of the system’s unannounced schedule. The survey team leader compiles the information necessary to support the corporate summation. One team leader is assigned for every 15 sites.

Through the multiorganization option, The Joint Commission accredits the individual health care organizations that are part of a multiorganization system, not the system itself. Therefore, each organization within a system receives its own accreditation decision and Accreditation Survey Findings Report. The findings and decision for one organization within a system have no bearing on those of another organization within the system.

**Concurrent Survey Option**

The Joint Commission offers a concurrent survey option for health care systems with more than one accredited laboratory included in a single system even if the organizations maintain different HCO numbers. This option provides a structure across the entire system and has the following components:

- Unannounced surveys of participating organizations occur at the same time
- Each participating organization must demonstrate compliance with all Joint Commission requirements independent of any other organization within the system
- Each organization with a distinct HCO number will receive a separate survey report and accreditation decision

The concurrent survey process works best when conducted in systems where 12 or fewer entities wish to be surveyed at the same time.

**Simultaneous Survey Option**

When an organization has both the hospital and the laboratory accredited by The Joint Commission, the survey dates will occur in the same year every 6 years. If the survey windows overlap each other, the organization can elect to have a simultaneous survey.

The HAP or AMB and Lab survey teams will be separate but will conduct a joint entrance conference and confer during the survey process. During tracer activity, if an
issue is identified that potentially impacts another program, surveyors will communicate relevant information. When possible, the same patient tracer may be used by both the laboratory and hospital surveyors. This will allow both surveyors to focus in their respective areas more efficiently and give the organization an enterprise-wide view of their processes.

JOINT COMMISSION STANDARDS AND ACCREDITATION

You can help drive standards development
The Joint Commission is the only organization that actively asks you for input into the standards. There is also a careful analysis of the rapidly changing health care field reflecting state-of-the-art technology and reasonable guidelines that every laboratory should strive to meet. Our standards undergo extensive review by the Laboratory Professional and Technical Advisory Committee (PTAC) composed of experts in the field of laboratory medicine, as well as extensive field review from our customers with final review by our Standards and Survey Committee and our Board of Commissioners prior to publication. Members of the Laboratory PTAC are drawn from representatives of national bodies such as:

- The American Academy of Family Physicians
- The American Association for Clinical Chemistry
- The American Association for Respiratory Care
- The Centers for Medicaid and Medicare Services
- The American Association of Bioanalysts
- The American Association of Blood Banks
- The American Society for Clinical Laboratory Science
- The American Society for Clinical Pathology
- The American Society for Cytotechnology
- The American Society for Microbiology
- The American Society of Histocompatibility and Immunogenetics
- The Centers for Disease Control and Prevention
- The Society for Assisted Reproductive Technology
- The Clinical Laboratory Standards Institute
- National Society for Histotechnology

Additionally, we have a Lab Advisory Council, composed of laboratory administrators from currently accredited labs to obtain feedback and to solicit potential improvements to the accreditation process.

The standards manual is available in two formats:
Hard copy -- The Joint Commission’s Comprehensive Accreditation Manual for Laboratories and Point of Care Testing (CAMLAB) is the place to begin when preparing for accreditation. The CAMLAB contains functional standards that are organized around the flow of services provided in a laboratory. The rationales and elements of performance will show you how to understand what the standards mean, how you can show compliance, and how your performance on the “Direct Impact Requirements" may
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affect your accreditation decision. Accredited organizations receive a copy of the standards as part of their accreditation fees and manuals are usually shipped in the last quarter of each year for the following year.

Electronic -- The E-dition is an electronic version of the Comprehensive Accreditation Manual for Laboratories and Point of Care Testing (CAMLAB). E-dition is a powerful database that provides the most up-to-date standards, and allows you to tailor the display of standards that apply to your organization. Filtering of information, e.g., selecting just certain specialty standards, to create a printable checklist is just one of the benefits of the E-dition. A single user license is provided to each organization as part of their accreditation fees.

Scoring and Decision Process for Laboratories: Criticality Model
The Standards Improvement Initiative (SII) provided The Joint Commission with the opportunity to refine the scoring and decision processes to be more objective. The new scoring and decision model is based on the criticality of the standards and other requirements which focuses the survey on the outcome of laboratory services and the impact to safe, quality care. The model permits leaders to prioritize their compliance activities and resource needs by stratifying the standards requirements in risk-based categories.

Criticality is defined as the immediacy of risk to patient safety or quality of care as a result of non-compliance with a Joint Commission requirement (for example, an Element of Performance (EP) or a National Patient Safety Goal (NPSG). The more critical the requirement, the more there is a potential risk to patient care or safety and the more immediately the issue of noncompliance needs to be resolved. The levels of criticality fall into four categories:

**Scoring Categories**
1. Immediate Threat to Health and Safety
2. Situational Decision Rules
3. Direct Impact Standards Requirements (adverse accreditation decision is based primarily on non-compliance with Direct Impact Standards)
4. Indirect Impact Standards Requirements
Below is a representation of the four levels of criticality within the new scoring:

A description of each scoring category follows:

1. Immediate Threat to Health and Safety
   Due to the immediacy of this circumstance, in the event of an “Immediate Threat to Health and Safety” situation, an expedited decision of Preliminary Denial of Accreditation (PDA) is issued by The Joint Commission president. The PDA decision remains in effect until corrective action is validated during an on-site, follow-up survey. After corrective action is validated, the laboratory’s accreditation status will change to Contingent Accreditation.

   Examples of Immediate Threat to Health and Safety findings are as follows:
   - Inoperable fire alarm
   - Patients with known antibodies received transfusions without the units being typed for the corresponding antigens

2. Situational Decision Rules
   Based on specific situations at the time of survey, a recommendation of PDA, Accreditation with Follow-up Survey, or Contingent Accreditation for the laboratory is made. Laboratories that receive a Contingent Accreditation decision must demonstrate
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resolution of identified issues through ESC submission **within 45 days** and have a follow-up, on-site survey to validate implementation of the corrective action.

Examples of Situational Decision Rule findings are as follows:
- Evidence of an unlicensed facility
- Unlicensed individual who requires a license

3. Direct Impact Requirements
Direct Impact Requirements are based on implementation of care processes. A requirement has a Direct Impact if noncompliance is likely to create an immediate risk to patient safety or the quality of care being provided. The difference between Direct Impact and other requirements is that the direct risk usually results because there are no or few processes (or no or few protective defenses) intervening between the noncompliance and the impact on the safety or quality of a patient’s care. If one or more Direct Impact EPs under a standard are found to be partially or insufficiently compliant, then all EPs under that standard, which have been found to be partially or insufficiently compliant, must be addressed in an ESC submission **within 45 days**.

Examples of Direct Impact findings are as follows:
- Failure to validate whether a new test, method or instrument used to report patient test results will consistently produce accurate results; failing to maintain at least a minimum blood supply (transfusion service); or, lack of a quality control program for each specialty and subspecialty of the pathology and clinical laboratory services. These requirements are in the lab accreditation manual.

4. Indirect Impact Requirements
Indirect Impact Requirements are based on planning and evaluation of care processes. A laboratory’s failure to resolve these compliance issues increases risk to patient safety or quality of care over time. This includes a risk that may ultimately exceed, in scope or severity, the noncompliance with a Direct Impact standard. If no Direct Impact EPs under a standard are found to be partially or insufficiently compliant, then all EPs under that standard, which have been found to be partially or insufficiently compliant, must be addressed in an ESC submission **within 60 days**.

Examples of Indirect Impact findings are as follows:
- Lack of documentation for ongoing staff education, lack of documentation for calibration verification procedures is not yet complete, and, the written report (for an adverse transfusion reaction workup) has not yet been made a permanent part of the patient’s record.

What are the accreditation policies for laboratories?

**Observed but corrected on-site during survey**
“Observed-but-corrected-on-site” RFIs will be a part of the organization’s report and must be addressed via the Evidence of Standards Compliance Report (ESC), but they will not be factored into the organization’s accreditation decision.
Findings that are appropriately documented as "Observed but Corrected On-Site" have the following characteristics:

- The deficiencies are easily corrected and do not pose a significant threat to patient safety.
- The correction should not require any organizational planning or forethought.
- The practice is correct but the policy needed amending to coincide with the practice, so the policy was amended.
- Corrections to a form that was missing an element or piece of information and the change would not impact the process.

**Examples of when “Observed but Corrected On-Site” IS applicable:**

- Gap in ceiling tile that is repositioned
- Partially burned out exit light that is corrected on discovery
- Multi-dose vial that is not dated—vial disposed of
- An expired QC strip could be disposed of immediately
- Refrigerator logs missing a few dates, but temperatures before and after missing dates are within range—no evidence of any trends (could be applied to other types of logs)
- Missing primary source verification for 2006 but the 2008 is present—evidence that the person in question has current licensure

**Examples of when “Observed but Corrected On-Site” is NOT applicable:**

- A policy is written or amended during survey that requires change in practice, education of staff and/or implementation
- Fire door fails to latch
- Refrigerator logs with temperatures out of range and no apparent action to correct or determination if medications or food are appropriate for use
- Proficiency testing issues

The organization’s accreditation status is not directly determined by that of the laboratory.

Any adverse laboratory accreditation decision does not have an immediate, direct impact on the hospital or overall organization’s accreditation decision.

Any adverse laboratory accreditation decision, whether due to lab survey by The Joint Commission, CAP, or COLA, will help prioritize The Joint Commission-accredited hospital’s or other organization’s next unannounced survey in that hospital’s or organization’s 18 – 36 month survey window, via the current hospital Priority Focus Process.

**Proficiency Testing Enrollment**

The Joint Commission and the Clinical Laboratory Improvement Amendments (CLIA) require that labs enroll with a CMS approved proficiency testing program for each regulated analyte performed. Annually, organizations accredited under The Joint Commission’s Laboratory Accreditation Program are required to submit documentation.
Excellence in Laboratory Accreditation

attesting to enrollment in proficiency testing via the secure Joint Commission Connect website. This documentation is required by January 31.

For more information see the following:
- Proficiency Testing Worksheet
- Proficiency Testing Enrollment Checklist
- Attestation Form
- Regulated Analytes

These forms are available on our internet site at: http://www.jointcommission.org/accreditation/lab_proficiency_testing.aspx

For questions regarding the requirement to submit documentation of annual enrollment in proficiency testing, please call (630)792-5248 or e-mail The Joint Commission at estawczyk@jointcommission.org.

Lab Central Connect™

The Joint Commission provides a unique portal that provides the laboratory with a centralized location to store documents associated with a lab’s accreditation survey. There are several pieces of information that are required to be entered due to their importance to the survey. These are:

- Key personnel (laboratory director, clinical consultant, technical consultant, and general supervisor) as applicable for the CLIA certificate complexity
- Test systems used for performing non-waived testing
- Cytology workload and annual statistics
- Whether you accept referral testing as this will drive applicable law in some states

In addition, you have the option of entering other documents needed for a survey such as validation plans, CLIA certificates, education documents, competency files and correlations. An optional Lab Operations module also has extended options for temperature monitoring, reagent logs, and competency monitoring. All of these modules are included within the regular accreditation fee.

Lab Central Connect is available to staff assisting with the intracycle monitoring events to allow laboratories to share documents if desired to enrich those conversations.

A separate security access is provided for Lab Central Connect to ensure that staff needing to access it but not the organization’s accreditation documentation can do so. This also allows your staff to access valuable tools such as the Leading Practice Library where other customers share procedures, BoosterPaks which give a deeper background on selected standards such as specimen collection, and an electronic version of the Lab standards.
Proficiency Testing Monitoring
The Joint Commission and the Clinical Laboratory Improvement Amendments (CLIA) require you to maintain successful performance on proficiency testing (PT). The Joint Commission receives unsuccessful proficiency testing performance data from CMS and directly from the PT providers for all regulated analytes through an electronic communication link. Unsuccessful performance is defined as a failure to achieve satisfactory performance for two consecutive or two out of three consecutive testing events. The following are considered unsuccessful proficiency testing performance:

- Failure to attain a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and D (Rho) typing and compatibility testing for two consecutive or two out of three consecutive testing events.
- Failure to attain a score of at least 100% for ABO group and D (Rho) typing or compatibility testing for two consecutive or two out of three consecutive testing events.

When unsuccessful proficiency testing occurs, a letter will be posted to the organization’s secure Joint Commission Connect site to request a Plan of Action. Laboratories will be asked to submit information including, but not limited to the following:

- Current and Historical PT Reports
- Analysis and corrective action of the unacceptable proficiency testing results
- Steps taken to assure the accuracy and reliability of patient results
- Review and approval of the corrective action by the laboratory director named on the CLIA Certificate

If the problem cannot be resolved, an on-site evaluation may be conducted which may ultimately affect your accreditation status. An on-site evaluation may also be conducted for extreme problems or those that jeopardize patient safety. At any time during the process, the lab may voluntarily discontinue testing. If the laboratory decides to voluntarily discontinue testing, the project manager at the Joint Commission must be notified in writing. The laboratory may not reinstate testing until the Criteria for Reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing. Reinstatement criteria include, but are not limited to, evidence of satisfactory performance on two proficiency testing events.

If the Plan of Action is acceptable, a letter will be posted to the organization’s secure Joint Commission Connect site. Proficiency testing monitoring will continue. The laboratory will be required to submit copies of the next two consecutive proficiency testing events.

If the laboratory fails to achieve satisfactory performance on one of the next two events, the laboratory must cease testing for a minimum of six months after the notice is issued for the testing specified. The laboratory may not resume testing until the Criteria for Reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.
A full description of the “Requirements for Accreditation” may be found in the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing in the “Accreditation Participation Requirements” chapter.

For questions or notifications regarding unsuccessful proficiency testing and submission of corrective plans of action, please contact Eileen Stawczyk, Project Manager, by phone at (630)792-5248, via e-mail at estawczyk@jointcommission.org, or in writing at The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, IL 60181.

**Reporting organization changes during the application process**

At any time during the accreditation process, a laboratory may undergo a change that modifies the information reported in its Application for Accreditation. The organization must notify The Joint Commission in writing within 30 calendar days after such a change is made using the Laboratory Organization Update Form available at [http://www.jointcommission.org/Laboratory_Organization_Update_Form/](http://www.jointcommission.org/Laboratory_Organization_Update_Form/). Information that must be reported includes any of the following:

- A change in ownership
- A change in location
- A change in laboratory director (can also be made through Lab Central Connect)
- A change in CLIA certificate type
- A significant increase or decrease in the volume of services or individuals served
- The addition of a new type of specialty or sub-specialty, program, or site of care
- The deletion of an existing specialty or sub-specialty, program, or site of care
- The addition of any high-complexity testing to the test menu
- The acquisition of a new component, for example, a new CLIA certificate
- The deletion of an existing component, for example, a new CLIA certificate

Note that certain changes may also need to be reported to your state agency. The Joint Commission may schedule an additional survey for a later date if its survey team arrives at the organization and discovers that a change was not reported. The Joint Commission may also review any unreported services addressed by its standards. In either event, there may be additional fees assessed. Please contact your assigned account executive, or the main number at (630) 792-3007.
THE JOINT COMMISSION SURVEY PROCESS

What are the resources available to laboratories preparing for accreditation?
The Joint Commission and its affiliate, Joint Commission Resources, offer a wide variety of products and services to clarify standards and help you prepare for accreditation:

- **The Standards Interpretation Group (SIG)** is responsible for answering specific questions about any standards and how they are interpreted. This is a no-cost service that you can access over the phone or through the Joint Commission website. Call (630) 792-5900, Option 6, or use the online form at [http://www.jointcommission.org/standards_information/standards_online_question_form.aspx](http://www.jointcommission.org/standards_information/standards_online_question_form.aspx). Be sure to request assistance from a laboratory specialist.

- The Joint Commission website contains **Frequently Asked Questions (FAQs)** for many areas of potential concern for laboratories. Many of these questions are posted by the Standards Interpretation Group, so you may be able to find your answers by checking the FAQs before calling or e-mailing SIG. In addition, compliance tips are listed and regularly updated on our website. [http://www.jointcommission.org/standards_information/jcfaq.aspx](http://www.jointcommission.org/standards_information/jcfaq.aspx)

- Every lab customer is assigned an **account executive** who acts as their liaison to The Joint Commission. Your account executive is there to assist you with your application and serve as a single point of contact to find the right answers to your questions.

**Joint Commission Resources (JCR)**

JCR, an affiliate of The Joint Commission, produces numerous publications, education programs, online tools and videos to help your organization successfully prepare for your upcoming survey. A brief list of their products is listed below. For a complete list of products or to obtain ordering information please visit their website, [www.jcrinc.com](http://www.jcrinc.com) or call their Customer Service department at (877) 223-6866.

**Education Programs**

Various laboratory education programs are held throughout the year. Go to [www.jcrinc.com](http://www.jcrinc.com) for an up-to-date list of titles, locations and dates.

**Publications**

*Comprehensive Accreditation Manual for Laboratory and Point of Care Testing (CAMLAB)*

This is the official book of standards for laboratories that includes all the information you need to meet accreditation requirements. Organizations who apply for accreditation receive one copy of this book as part of their application fee.
Excellence in Laboratory Accreditation

The Accreditation Process Guide for Laboratories
This comprehensive guide shows you what happens, and when, during the onsite accreditation survey. It includes examples of questions that may be asked by the surveyor, and suggested documentation to have available at every step.

Software
Accreditation Manager Plus Laboratory
This is the software solution for managing your continuous compliance preparation process. In addition to having all the content of the Comprehensive Accreditation Manual, Accreditation Manager Plus provides a central location for all of your accreditation activities including scoring, project management and managing local information. When it comes time to complete your organization’s Periodic Performance Review, simply export your AMP scoring data to The Joint Commission site.

E-dition Laboratory
The Joint Commission E-dition is your convenient source for online access to the Joint Commission standards and requirements. E-dition provides a single central resource for the latest standards. Use features like filtering and service profiles to tailor the view to your needs. Full-text searching provides quick access to topics. Guarantee your staff has access to all the benefits of E-dition at any time by upgrading to a site license.

What are the qualifications of the Joint Commission’s laboratory surveyors?
Joint Commission laboratory staff and field surveyors are experienced laboratory professionals who understand the day-to-day issues that confront you, and have the hands-on expertise to help you resolve them. The Joint Commission on-site survey is conducted by one or more medical technologist(s), as determined by the laboratory’s scope of services. Surveyors often have their Master’s degree and past experience as laboratory managers. A pathologist may also be added to the team to review cytology and histology.

The Joint Commission ensures surveyor consistency by providing comprehensive initial training and a minimum of 10 days of continuing education annually to keep surveyors up-to-date on evolving technologies and advances in quality-related performance evaluation. New surveyors are assigned to tenured surveyors and must complete an acceptable preceptorship. All surveyors have passed a rigorous Certification Exam. Additionally, all laboratory surveyors attend a week-long annual conference and participate in on-going distance learning events structured to build on their standards and accreditation process expertise.

Focus on the accreditation survey as an educational, consultative process is emphasized. The Joint Commission emphasizes that staff be collaborative, aspirational and relevant in their behavior and relationships with customers.
Excellence in Laboratory Accreditation

The Joint Commission encourages our customers to evaluate their surveyors’ performance. That performance is also evaluated continually throughout the year by our Field Directors.

**What are the different types of laboratory surveys?**

In lieu of a traditional initial accreditation survey, a laboratory that wants to be accredited for the first time by The Joint Commission may alternatively choose the Early Survey Policy Option outlined below. Note that Early Survey Option 1 is required for all new laboratories in the State of Florida.

Under both options, a laboratory is required to undergo two surveys. However, the nature of the surveys and potential outcomes differ. The first survey under Early Survey Policy Option is a more limited survey, while the first survey under Option 2 is a full accreditation survey.

**a) Early Survey Options**

*Early Survey Option 1:*
- Licensed
- Conducted up to two months before opening
- Announced
- Limited set of standards
- Decision: Preliminary Accreditation
- Four months later, another survey
- Full survey
- Decision: appropriate change in decision status based on survey outcome

*Early Survey Option 2:*
- Conducted when an organization has been in operation at least one month, has cared for at least 10 patients, and has at least one active patient.
- Unannounced
- Full survey; no track record achievement required
- Decision: based on survey outcome
- Four months later, full, follow-up survey
- Addresses track record and standards compliance issues
- Decision: based on survey outcome

Please contact your account executive for additional information.

**b) Unannounced surveys**

With some exceptions, e.g., Department of Defense laboratories, freestanding in-vitro fertilization labs, “very small laboratories” performing < 5,000 tests annually, labs undergo an unannounced survey that will take place anytime within six months prior to the lab’s resurvey accreditation due date. The unannounced survey is not applicable to initial surveys, only to the biennial re-survey and for-cause surveys.
Unannounced surveys promote continuous compliance with the standards and allow the surveyor to assess the organization on routine days. The unannounced survey process also removes the expense and the stress of preparation by promoting continuous readiness.

**What are the key components that guide the on-site survey?**
The tracer methodology is the cornerstone of the Joint Commission on-site survey. The tracer methodology does the following:

- The surveyor(s) will follow the patient’s experience, looking at services provided by various individuals and service areas within the laboratory, as well as ‘hand-offs’ between them.
- Follows the experience of care of individuals through the pre-analytical, analytical, and post-analytical laboratory processes.
- Allows the surveyor to identify performance issues in one or more steps of the process, or in the interfaces between processes.

The surveyor(s) will select patients and specimens from an active patient list and ‘trace’ their service experience. Patients typically selected are those who have received lab tests requiring collection of multiple specimens. This type of review is designed to uncover systems issues.

The survey will review all specialties and subspecialties. Surveyors will select a tracer for at least one patient per Clinical Service Group (CSG) and at least one tracer must be included for each piece of testing equipment. The number of patients and specimens followed under the Tracer Methodology will depend on the size and complexity of the organization’s laboratory services, and the length of the on-site survey.

**What is the agenda for a typical on-site survey?**
Although a survey is geared to your laboratory’s specific needs, certain features are common to all initial surveys. Surveyors do not judge items or situations not relative to the standards. Although they may make suggestions outside the scope of the standards, such advice is purely educational. However, when any aspect of the laboratory operation is considered to be a threat to the health and safety of patients, staff, or visitors, the findings may be considered for accreditation purposes even if they are not directly addressed in the standards.

Notification of the initial survey is posted to the organization’s secure extranet site 30 days prior to the survey. Re-surveys are unannounced, with few exceptions.

All surveys are at least one day in duration. However, depending on the size and the scope of the laboratory services provided, a survey may last five days or more. A typical survey of a laboratory in a medium-sized acute care hospital involves one surveyor and lasts two to three days.

As previously mentioned, one to two weeks before survey, the assigned medical technologist surveyor will contact the laboratory to discuss the survey schedule. (PLEASE
The following charts outline what happens in the key components of a survey.

<table>
<thead>
<tr>
<th>Surveyor Arrival &amp; Preliminary Planning Session - 30 min</th>
<th>Procedure</th>
<th>Joint Commission surveyors will display their ID badge and direct the organization to their Joint Commission Connect site to verify the survey.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who should participate from your organization?</td>
<td>Laboratory Survey Coordinator and Senior Leadership</td>
<td></td>
</tr>
<tr>
<td>What should organizations have available?</td>
<td>(SEE Document List on page 33)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opening Conference- 15 min</th>
<th>This conference, which is held on the first day of the survey, is a meeting between key laboratory staff and the surveyor(s).</th>
</tr>
</thead>
</table>
| Purpose                    | • Explain the structure of the survey.  
                              • Describe each component of the survey agenda and make any changes, if necessary.  
                              • Answer any questions about the organization has about the survey. |
| Who should participate from your organization?           | • CEO  
                              • Other senior leadership designated by organization  
                              • Lab Director(s) on all CLIA Certificates  
                              • Lab Administrative Director and/or Manager  
                              • Survey coordinator  
                              • Other lab staff designated by organization |

<table>
<thead>
<tr>
<th>Orientation to the Organization-45 min</th>
<th>During this session, organization and laboratory leaders will explain the organization’s purpose and structure to the surveyor(s).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who should participate from your organization?</td>
<td>• Same participants as Opening Conference</td>
</tr>
</tbody>
</table>
| What will occur?                      | The organization will have the opportunity to describe its basic structure, mission, vision, scope of care, patient population(s), and strategic planning approach to the surveyor(s), and to describe the laboratory testing and point-of-care service’s role within the organization. This activity is led and structured by the surveyor.  
                              At the conclusion of the Opening Conference, the surveyor will ask staff members to talk about how the organization provides required laboratory testing services, focusing on management, oversight, and important processes and functions. |

<table>
<thead>
<tr>
<th>Regulatory Review-30 min</th>
<th>This review is to verify that licensing and services provided by the laboratory comply with law and regulation.</th>
</tr>
</thead>
</table>
| Who should participate from your organization? | • Lab Director(s) on all CLIA certificates.  
                              • Lab Administrative Director and/or Manager.  
                              • Other lab staff as designated by organization. |
| Purpose                  | • Verify that the laboratory is performing services according to |
### Excellence in Laboratory Accreditation

| applicable federal and state laws and regulations |
| Review Clinical Laboratory Improvement Amendments (CLIA) certificates, specialties, and sub-specialties |
| Review state licenses, as required, of the laboratory and/or personnel |

**What will occur?**

- The surveyor will verify the annual test volume submitted in the Application for Accreditation meet CMS Guidelines for Counting Tests for CLIA.
- The surveyor will review the information on the laboratory test volume and specialty report volume for each CLIA identification number and compare it to the application information. If a CLIA identification number has been discontinued following the submission of the Application for Accreditation and prior to the survey, the surveyor will collect the reason and effective date for the discontinuation of the CLIA identification number.
- The surveyor will validate that the laboratory is performing testing appropriate to the complexity level of the CLIA certificate.
- The surveyor will confirm that the medical director on the certificate is the current director and is qualified for that level of directorship. (Note: If the current director is not identified on the CLIA certificate, the laboratory must provide evidence that CMS was advised of the change.)

**What documents need to be available?**

- CLIA certificates for all laboratory testing sites being surveyed
- Documentation of personnel licenses or certification, if required by the state

### Proficiency Testing Validation / Performance Improvement Data Review-60 – 120 min

| Who should participate from your organization? |
| Laboratory Director(s) on all CLIA Certificates |
| Laboratory Administrative Director and/or Manager |
| Laboratory supervisory/lead staff, as required |

| What will occur? |
| Verification that the lab is enrolled and participates in a CMS-approved proficiency testing program for each regulated analyte. |
| Review of proficiency testing performance for regulated analytes and non-regulated analytes (if applicable), including documentation of remedial action for each result exceeding acceptable limits. |
| Review of policy, attestation sheets, and applicable work records. |
| Review performance improvement policy and data. |

| What documents need to be available? |
| All proficiency testing results for the last 24 months (six events) |
| All records of test handling, preparation, processing, examination, and results reporting and signed attestation statements provided by the proficiency feedback reports |
| Documentation of review of each proficiency report and documentation of intensive review of problems or potential
### Surveyor Planning Session-15 min

The surveyor(s) will review data and information about the laboratory, measures of success generated from the full ICM, option 1, or option 2, and plan the survey agenda. The surveyor(s) will also select initial tracer patients. As part of the survey process, surveyors will review the laboratory’s MOS information.

**Purpose**
- Give surveyors time to look at information (such as priority focus areas [PFAs] and clinical service groups [CSGs]) and the equipment and test list that affects the survey agenda.
- Plan the agenda for the survey.
- Select initial patient tracers.

**Who should participate from your organization?**
Ideally, the laboratory survey coordinator (who may also be the laboratory manager) should be available if the survey team has questions, although this person does not directly participate in this session.

**What needs to be available?**
- An organization chart and map of the organization (if available)
- Access to patients records who have had laboratory tests or other
- Performance Improvement Data
- Proficiency testing data
- Results of periodic laboratory environment inspections from the safety committee or safety officer
- List of laboratory specialties or departments in the laboratory, a list of instruments, test menu, and a list of all sites performing laboratory tests

### Individual Tracers—length of time allotted is dependent on length of survey

**Who should participate from your organization?**
Appropriate laboratory and other organization representatives and care providers in the settings the surveyor visits.

**Individual-based System Tracers**
As surveyors go through the individual tracers to determine standards compliance as it relates to laboratory services delivered to the selected patient, they also assess the organization’s overall systems by conducting individual-based system tracers. Individual system tracers focus on high-risk processes across the organization. The current individual based system tracers are data use and infection control.

**Purpose**
To evaluate the laboratory’s compliance with standards as they relate to the care, treatment, and services provided.
- Follow the course of a laboratory service provided to a patient by and within the organization
- Assess the interrelationships among disciplines, departments, or units and the important functions in the care and services being provided
- Evaluate the performance of relevant processes, with particular focus on the integration and coordination of related processes
- Identify strengths and concerns in the relevant processes
### What will occur?

The surveyor will visit all areas of the organization that affect the delivery of a laboratory service, including areas where orders are written or received, specimens are collected and processed, testing is performed, and results are documented and communicated. For blood transfusion services, the surveyor will visit patient care areas where blood is being transfused to review the functions that accompany this process.

The surveyor will begin the tracer with the test result, and then he or she will follow the entire testing process for that patient from pre-analytic through post-analytic processes. Tracers will be selected on the basis of the mechanism by which samples are collected and should include at least one of each of the following, as applicable:
- Outpatient sample collected by laboratory personnel
- Outpatient sample collected by non-laboratory personnel and transported to the laboratory
- Inpatient sample collected by laboratory personnel
- Inpatient sample collected by patient care personnel
- Sample sent to a reference laboratory
- Specimen from an Emergency Department patient

The surveyor will follow up on observations made during the tracer to determine whether the observations reflect an isolated experience or a pattern of performance.

At the conclusion of the tracer, the surveyor may communicate any specific observations made to the staff and explain that overall scoring of these issues will reflect other tracer visits and assessment activities.

### What documents need to be available?

The surveyor will require the medical record, test requisition, lab equipment records, quality control records, laboratory test reports, and staff competency and education records for the patient who is the subject of the tracer. He or she may also want to review additional records near the end of the activity based on the criteria described earlier.

---

### Competence Assessment Process-60 min

This process will help the laboratory and the surveyor(s) do the following:

1) Learn more about the laboratory’s competence assessment process for staff, licensed independent practitioners, and other credentialed practitioners.

2) Learn more about the organization’s orientation, education, and training processes as it relates to staff, licensed independent practitioners, and other credentialed practitioners encountered during Individual Tracer.

3) Discuss competence assessment process-related strengths and potential risk points.

### Who should participate from your organization?

- Human resource processes
### Environment of Care Tour

The surveyor will tour the main laboratory (if it is to be included in the survey), assessing the space and evaluating for environmental issues. This is an interactive tour between the surveyor and supervisory and other staff. Any staff may be interviewed about safety or other environmental issues.

#### Purpose
- Orient the surveyor to the laboratory’s environment, including the equipment used and services provided
- Give the surveyor an opportunity to observe the following:
  - The laboratory’s performance in managing EC risk
  - Adequacy of space and resources for services provided
  - Implementation of infection control processes
  - Implementation of laboratory environment safety processes as defined in policies
  - Methods of intra-laboratory and organization-wide communication
  - Enforcement of a nonsmoking policy
  - Adequacy of the number of staff members

#### Who should participate from your organization?
- Safety Management Coordinator
- Security Management Coordinator
- Facility Manager
- Building Utility Systems Manager
- Organizational leadership
- Laboratory Manager
- Section leader/supervisors
- Laboratory director(s) on all CLIA Certificates

#### What will occur?
The surveyor will visit the areas of the organization where laboratory services are provided. A comparison will be made between the types of services provided and those listed on the survey application to ensure all have been included on the survey agenda. During the walk-through, the surveyor will also make initial observations regarding such functions as laboratory safety and infection control, laboratory security, safety equipment, laboratory space and configuration, storage of chemicals, management of information, and leadership. The surveyor may interview staff about safety and infection control practices, equipment use, hazardous materials use and waste disposal, and security of information.

### Special Issue Resolution Option-30 min (multi-day surveys only)

This activity is performed when surveyors need to resolve issues that have been identified during other survey activities or when more time is needed to address a specific topic.

#### Purpose
This activity allows surveyors to clear up any outstanding issues related to topics that have arisen during the survey.

#### Who should participate from your organization?
Participants from the organization will vary depending on the issue(s) to be addressed.

#### What will occur?
The number of sessions scheduled may vary according to laboratory service, size, and complexity. Depending on the issues to be addressed, surveyors may wish to do one or a combination of the following:
- Review additional records to confirm a tracer finding
### Excellence in Laboratory Accreditation

- Review human resources or credentials files
- Review measures of success
- Hold discussions with staff members in a specific area
- Review policies and procedures
- Remind the laboratory of any promised items that the surveyor is still waiting for them to provide for review

#### Daily Briefing Option-30 min (multi-day surveys only)

<table>
<thead>
<tr>
<th>Purpose</th>
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<tbody>
<tr>
<td>Helps leaders understand the survey process and the findings that contribute to the accreditation decision</td>
</tr>
<tr>
<td>Offers a concise summary of survey process activities completed during the previous day’s activities</td>
</tr>
<tr>
<td>Highlights positive findings or exemplary performance</td>
</tr>
<tr>
<td>Describes any patterns or trends of significant concern that could lead to a decision of noncompliance</td>
</tr>
<tr>
<td>Gives staff an opportunity to provide information that may have been missed during the previous survey day</td>
</tr>
<tr>
<td>Allows the surveyor(s) to review the survey agenda for the present day and make any necessary adjustments based on organization needs or the need for more intensive assessment of a specific issue.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who should participate from your organization?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The chief executive officer (CEO) or other representative from administration</td>
</tr>
<tr>
<td>Senior laboratory and other involved leaders</td>
</tr>
<tr>
<td>Other staff designated by the laboratory director or manager</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>What will occur?</th>
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<tbody>
<tr>
<td>All Joint Commission surveyors who are on site will participate in the daily briefing. When several surveyors are present, one will act as facilitator for the briefing. He or she will give a concise summary of the previous day’s survey activities and make general comments regarding any significant issues resulting from those activities. The surveyor(s) will not go into detailed explanations of findings at this time; however, the organization may ask to include a session for more intensive discussion in the survey agenda. The organization may also ask for an educational session on specific compliance issues; surveyors will honor these requests as far as time allows.</td>
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</table>

#### Surveyor Report Preparation-90 min

<table>
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<th>Purpose</th>
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<tbody>
<tr>
<td>To allow the laboratory one final on-site opportunity to clarify and clear observations and findings.</td>
</tr>
<tr>
<td>Revise documentation of findings that were observed but the laboratory has corrected while the surveyor is on site, as allowed.</td>
</tr>
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</table>

#### CEO Exit Briefing and Organization Exit Conference-30 – 45 min

<table>
<thead>
<tr>
<th>Purpose</th>
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<tbody>
<tr>
<td>Report the outcome of the survey to senior leaders and present the accreditation report, if desired by the laboratory</td>
</tr>
</tbody>
</table>
### Excellence in Laboratory Accreditation

| Who should participate from your organization? | Senior leaders from the organization laboratory, the CEO, and/or another senior representative  
Laboratory Directors on all CLIA Certificates |
| What will occur? | The surveyor(s) will use the accreditation report as the basis for conducting this activity, even if the laboratory medical director or CEO does not permit the distribution of the printed report. The report is organized by chapter; therefore, the surveyors will present findings of partial and noncompliance following those groupings. They will also remind staff of the PFAs that were the focus of initial activities and note how changes (continuations, additions, or eliminations) were made as the survey went on.  
Next, the surveyors will address findings related to Accreditation Participation Requirements and National Patient Safety Goals. They will also comment on the areas where the laboratory services have performed well.  
Staff will have an opportunity to ask questions and present additional clarification evidence of compliance that may affect the findings.  
Finally, the surveyors will recap all standards and elements of performance that require the organization to submit an Evidence of Standards Compliance (ESC) report and, in some cases, a measure of success, to The Joint Commission.  
• The Joint Commission Central Office will accept no additional documentation except for the ESC submission; therefore, the organization should present any concerns it may have about survey findings during this conference. If the organization would like further clarification of the survey findings from the Central Office, it may request this with its ESC submission. |

- Review standards compliance issues that were identified during the survey.  
- Allow staff a final opportunity to question the survey findings or present or have surveyors review evidence of compliance while the surveyors are on site. (Note: If additional documentation is presented, the surveyor should review this material after completing his or her presentation of findings, but before concluding the exit conference.)  
- Reach agreement between the surveyor(s) and staff regarding the survey findings, when possible.  
- Review any follow-up actions that will be required. Note when Evidence of Standards Compliance and Measures of Success (MOS) are due from the laboratory.  
- Explain the ESC and MOS submission processes.  
- Explain when the final accreditation decision is made.  
- Explain when the official survey report will be posted on the Joint Commission Connect site.
Excellence in Laboratory Accreditation

Laboratory Accreditation Program
Document List

As a Laboratory, you will need the following information and documents available for the surveyor to review during the Surveyor Planning Session which occurs on the first day of survey:

**Note:** The 24-month reference in the following items is not applicable to initial surveys, except for proficiency data. For initial surveys, a minimum of 4 months of data must be available for review.

- Name of key contact person who can assist surveyors in planning tracer selections
- CLIA Certificates, Specialties and Subspecialties, State Licenses, and personnel licenses or certification if required by the state or the policy of the organization. (Needed for Regulatory Review)
- An organizational chart and map of the facility
- Ability to retrieve testing records for patients who have had laboratory tests or other services for the past 24 months
- Performance Improvement Data for the past 24 months
- Proficiency data by CLIA number for the past 24 months (required for initial and resurveys)
- Results of periodic laboratory environment inspections from the safety committee or safety officer and manifests for disposal of hazardous waste.
- A list of specialties and subspecialties performed by the laboratory, a list of tests performed (e.g. the test menu) and major instruments used by the laboratory service, including all other ancillary and point-of-care sites performing laboratory tests
- Measures of Success (MOS) identified in the Plan of Action from the Periodic Performance Review

Please note that this is not intended to be a comprehensive list of documentation that may be requested during the survey. Surveyors may need to see additional documents throughout the survey to further explore or validate observations or discussions with staff.

**Verification of Surveyor Identification**

Organizations will need to access their Joint Commission extranet site upon arrival of surveyors for an unannounced survey. This is accomplished by accessing the internet and the Joint Commission’s website (www.jointcommission.org) and clicking on The Joint Commission Connect. You will need to enter your Login ID and password to enter the organization’s secured Joint Commission website. Access the Notification of Scheduled Events link on your extranet site.

**IMPORTANT:** Your unannounced survey procedures should include the Login ID and password to access the organization’s secure extranet site, “The Joint Commission Connect.”

By 7:30 a.m. (local time) on the first day of the unannounced survey, the organization’s extranet site will contain:
Excellence in Laboratory Accreditation

- An introductory letter authorizing the surveyor’s presence for the unannounced survey
- Surveyor names, photographs, and biographies
- Survey dates
- Priority Focus Process output (most current version).

How are surveys scheduled and what if a postponement and delay is needed?
The Joint Commission tries to honor specifically-requested dates during which an organization prefers not to be surveyed. The organization should include these specific dates with the completed Application for Accreditation, whenever possible. There may, however, be circumstances that prevent The Joint Commission from accommodating these dates.

Definition of postponements and delays
The Joint Commission also provides for the postponement or delay of initial surveys. A postponement is an organization’s request to alter an already-scheduled survey date. A delay is an organization’s request to push back the survey date before it is actually scheduled. An organization should direct a request for a postponement or delay to your account executive.

Accepted Reasons for Postponement
An organization may postpone initial scheduled surveys when one or more of the following events happen:

- a natural disaster or another major unforeseen event occurs that totally or substantially disrupts operations;
- the organization is involved in a major strike, has ceased accepting patients, and is transferring patients to other facilities; or
- patients, the organization, or both are being moved to another building during the scheduled survey.

The Joint Commission reserves the right to conduct an on-site survey if the organization continues to provide patient care services under such circumstances.

An organization may also postpone an initial survey when The Joint Commission has provided it with less than four weeks advance notice of the survey date(s) in writing or by telephone.

Fees for Postponements
The Joint Commission may approve a survey postponement for an organization not meeting any of the postponement criteria described above if the organization pays a fee to defray costs. The Joint Commission will charge the base fee for the survey of each program being postponed. The Joint Commission reserves the right, however, to deny any request for a postponement or delay, regardless of the organization’s willingness to pay the special fees.
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Length of Postponement or Delay
An initial survey ordinarily may be postponed or delayed for no more than six months. These situations are decided on a case by case basis.

AFTER THE SURVEY

Evidence of Standards Compliance (ESC)
After the survey, the surveyor(s) transmits their survey findings to The Joint Commission’s Central Office. Your laboratory’s official survey report will be posted on your laboratory’s secure extranet site as soon as the Central Office’s review is completed. Every Element of Performance (EP) found not in compliance at the time of survey will generate a requirement for improvement.

The 10-Day Clarification process provides organizations an opportunity to demonstrate compliance with standards that were scored as “Not Compliant” at the time of survey. Your organization is required to submit any clarifying evidence to The Joint Commission within ten business days of receiving your survey report. The clarifying evidence should be submitted via the Evidence of Standards Compliance tool. Clarifications may take either of the following forms:

• An organization believes it had adequate evidence available to the survey team and was in compliance at the time of survey. The organization may submit clarifying evidence to support that contention.
• The organization has detailed evidence that was not immediately available at the time of survey. The clarification must include an explanation as to why the surveyor(s) did not have access to the information or why it was not provided to the surveyor(s) at the time of survey.
• For category “C” Elements of Performance, the organization conducted a review and can demonstrate 90% or greater compliance.

For those Direct Impact Standards Requirements scored as non-compliant, the organization will have to submit Evidence of Standards Compliance (ESC) to The Joint Commission within 45 days (60 days for Indirect Impact Standards Requirements) of the completion of the survey. The ESC should detail the action that the laboratory took to bring itself into compliance with a standard for which it received a requirement for improvement. An ESC report must address compliance at the EP level and include a Measure of Success (if applicable).

Measure of Success (MOS)
For each Plan of Action to address an identified area of non-compliance, an organization will need to identify Measures of Success that can be used to validate resolution of the problem area. Measures of Success (MOS) are quantifiable, data-driven measurements that can show compliance with a standard or set of standards. When an EP with a noncompliant standard requires a Measure of Success (MOS), your organization must demonstrate achievement with the MOS when completing the ESC.
Excellence in Laboratory Accreditation

Not every EP requires an MOS. EPs that do require an MOS are clearly marked in the standards chapters in the accreditation manual.

What are the accreditation decisions?
The goal of the accreditation decision and reporting approach is to focus on the issues that pose the greatest risk to quality of care and patient safety. During the decision process, there are no numerical scores, and thus no scores are disclosed to the laboratories or to the public. The lack of scores facilitates shifting the focus from passing the exam to continuous operational improvement. Below are the six categories of accreditation:

Preliminary Accreditation results when a health care organization demonstrates compliance with selected standards used in the surveys conducted under the Early Survey Policy.

Accreditation is awarded to a health care organization that is in compliance with all standards at the time of the on-site survey or has successfully addressed all requirements for improvement (RFIs) in an Evidence of Standards Compliance (ESC) submission within 45 or 60 days following the posting of the Accreditation Survey Findings Report and does not meet any other rules for other accreditation decisions.

Accreditation with Follow-up Survey is awarded when a health care organization is not in compliance with specific standards that require a follow-up survey within 30 days to six months. The organization also must successfully address the identified problem area(s) in an ESC submission.

Contingent Accreditation results when a health care organization fails to successfully address all requirements of the Accreditation with Follow-up Survey decision. In most cases, a follow-up survey in 30 days will be required.

Preliminary Denial of Accreditation results when there is justification to deny accreditation to a health care organization due to one or more of the following: an immediate threat to health or safety for patients or the public; failure to resolve the requirements of an Accreditation with Follow-up Survey status after two opportunities to do so; failure to resolve the requirements of a Contingent Accreditation status; or significant noncompliance with Joint Commission standards. This decision is subject to review and appeal before the determination to deny accreditation.

Denial of Accreditation results when a health care organization has been denied accreditation. All review and appeal opportunities have been exhausted. More information about accreditation decisions, policies and procedures can be found in The Joint Commission’s accreditation manuals.
What tools are available to help my lab publicize our achievement?

Publicize your achievement of national accreditation and the Joint Commission's Gold Seal of Approval™ by notifying patients, the public, the local media, third-party payers, and resident referral sources. On our website The Joint Commission offers a free publicity kit that includes

- suggestions for celebrating your accreditation
- guidelines for publicizing your Joint Commission accreditation
- frequently asked questions
- sample news releases
- fact sheets

Information about your accreditation status will be posted in Quality Check™ on the Joint Commission website, www.jointcommission.org. Quality Check allows anyone to search for accredited organizations within a city or state, or by type of setting.

What is necessary to maintain my lab’s accreditation?

The accreditation process does not end when the on-site survey is completed. The Joint Commission requires ongoing self-assessment and corrective actions (see Periodic Performance Review).

When done successfully, continuous survey compliance means less focus on the ‘ramp up’ for survey every two years. Instead, organizations can and should continually improve their systems and operations, eliminating the need for intense survey preparation. Continuous compliance with the Joint Commission standards directly contributes to the maintenance of safe, quality care and improved organizational performance.

Intracycle Monitoring (ICM)

A non-punitive, Intracycle Monitoring (ICM) is required for Joint Commission accredited laboratories. This tool will be available, at no extra cost (if the organization picks an option 2 or 3 survey there will be a cost for the on-site survey), on a secure extranet site and is virtually a self-assessment process. The Joint Commission’s intent in implementing the ICM is to encourage laboratories to proactively assess performance, identify issues for improvement to embed the standards into your everyday performance in order to improve the safety and quality of patient care.

The standards reviewed in the tool are selected based on risk impact, and the laboratory can elect to review additional standards. The process will also include a discussion of Joint Commission tools and resources that may be of use to the organization, depending on its needs.

The ICM tool becomes available to laboratories seeking accreditation for the first time after submitting their e-App and deposit. Access to this tool will assist the laboratory in preparing for their initial survey. While utilizing the tool, these laboratories are eligible to
schedule calls with the Joint Commission Standards Interpretation Group for discussion regarding the laboratory standards and survey process.

Please contact your account executive for due dates, for help in accessing the ICM tool, and for information regarding the various ICM Options.

The process will also include a discussion of Joint Commission tools and resources that may be of use to the organization, depending on its needs.
Excellence in Laboratory Accreditation

FORMS

Laboratory Organization Update Form
The Joint Commission

Please complete this form to update The Joint Commission on changes in your organization. The form must be received at The Joint Commission within 30 days of any change. Please use your browser to print this form. Complete only the sections that apply to address the changes you are reporting. The laboratory director whose name appears on the CLIA certificate must sign this notification. Please mail the form to the address listed below or fax the form to your account representative.

*Please be advised that your state agency must also be notified of the following changes:

- Change in Certificate Type
- Site (laboratory) Address/Name Change
- Ownership
- Laboratory Director (as identified on CLIA certificate)

Do not notify your state agency (excluding Washington State) for the following changes related to a Certificate of Accreditation:

- Addition or Deletion of Specialties/Sub-specialties
- Addition of Tests or Examinations
- Deletions or Changes in Test Methodologies

Organization Information
Always complete this section
Joint Commission Healthcare Organization Identification Number:________________________
Organization Name:________________________________________________________________________
Address:_____________________________________________________________________________
City, State, Zip:________________________________________________________________________
Phone Number:_________________________________________________________________________
Lab Director’s Name:____________________________________________________________
Lab Director’s Signature:_____________________________________________________________
Date:______________________________________________________________________________

Please indicate the type of change

☐ Discontinuation/Removal of a CLIA Identification Number from an Organization’s Joint Commission Records
CLIA Number:______________________________________________________________
Laboratory Name:____________________________________________________________________
Address/Location:____________________________________________________________________
City, State, Zip:_____________________________________________________________________
Effective Date:_____________________________________________________________________
Select a Reason for the Discontinuation of the CLIA Identification Number:
☐ Laboratory Closed
☐ Laboratory No Longer Performs Testing
☐ Laboratory Seeking non-Joint Commission accreditation
   Name of Other Accrediting Organization:__________________________________________
☐ Laboratory Sold
☐ Other:__________________________________________________________________________
Excellence in Laboratory Accreditation

- **New Certificate of Accreditation CLIA Identification Number**
  
<table>
<thead>
<tr>
<th>CLIA Number:</th>
<th>Laboratory Name:</th>
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<tr>
<td></td>
<td>Address/Location:</td>
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<td></td>
<td>City, State, Zip:</td>
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<tr>
<td></td>
<td>Effective Patient Testing Date:</td>
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<tr>
<td></td>
<td>Specialty/Subspecialty Performed:</td>
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</table>
  
  Please see last page of form for CLIA Specialty and Subspecialty Information.

  Proficiency Test Provider(s), if applicable:_________________________
  Estimated Annual Test Volume:________________________

- **New Certificate for Provider Performed Microscopy Procedures (PPMP) CLIA Identification Number**
  
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<tr>
<th>CLIA Number:</th>
<th>Laboratory Name:</th>
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<td>Address/Location:</td>
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<td></td>
<td>City, State, Zip:</td>
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<tr>
<td>Test(s) Performed:</td>
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</table>

- **New Certificate of Waiver CLIA Identification Number**
  
<table>
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<th>CLIA Number:</th>
<th>Laboratory Name:</th>
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<td>City, State, Zip:</td>
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<td>Test(s) Performed:</td>
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- **Change in Certificate Type**
  
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<th>CLIA Number:</th>
<th>Laboratory Name:</th>
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<td>City, State, Zip:</td>
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<td>Effective Date:</td>
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<tr>
<td>Change from:</td>
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<tr>
<td>Certificate of Waiver</td>
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<tr>
<td>Certificate for Provider Performed Microscopy Procedures</td>
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<tr>
<td>Certificate of Compliance</td>
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<tr>
<td>Certificate of Accreditation</td>
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  | Change to: |
  | Certificate of Waiver |
  | Certificate for Provider Performed Microscopy Procedures |
  | Certificate of Compliance |
  | Certificate of Accreditation |

  If changing to a Certificate of Waiver or Provider Performed Microscopy Procedures (PPMP), please complete the information below:
  Test(s) Performed:__________________________________________________________
Excellence in Laboratory Accreditation

If changing to a Certificate of Accreditation, please complete information below:
Please see last page of form for CLIA Specialty and Subspecialty Information.
Specialty/Subspecialty performed:

Proficiency Test Provider(s), if applicable:
Estimated Annual Test Volume:

Note: Please be sure to add/delete the applicable test system(s) to your Lab Central Connect site. Lab Central Connect is available under the Continuous Compliance Tools section of your secure Joint Commission Extranet site.

- Add Specialty/Subspecialty to an existing Certificate of Accreditation CLIA Identification Number
  Please see last page of form for CLIA Specialty and Subspecialty Information.
  CLIA Number: _________________________________
  Laboratory Name: _______________________________
  Address/Location: _______________________________
  City, State, Zip: _________________________________
  Effective Patient Testing Date:
  Additional Specialty(ies)/Subspecialty(ies):
  If laboratory is adding virology, general immunology, or bacteriology, is the lab ONLY performing RSV (virology), Mono (general immunology), or Strep Screen (bacteriology) with a moderate complex methodology kit?
  Proficiency Test Provider(s), if applicable:
  Estimated Annual Test Volume:

  Note: Please be sure to add the applicable test system(s) to your Lab Central Connect site. Lab Central Connect is available under the Continuous Compliance Tools section of your secure Joint Commission Extranet site.

- Delete Specialty/Subspecialty from an existing Certification of Accreditation CLIA Identification Number
  Please see last page of form for CLIA Specialty and Subspecialty Information.
  CLIA Number: _________________________________
  Laboratory Name: _______________________________
  Address/Location: _______________________________
  City, State, Zip: _________________________________
  Effective Date:
  Deleted Specialty(ies)/Subspecialty(ies):

  Note: Please be sure to delete the applicable test system(s) from your Lab Central Connect site. Lab Central Connect is available under the Continuous Compliance Tools section of your secure Joint Commission Extranet site.

- Addition of high complexity testing to an existing Certificate of Accreditation CLIA Identification Number
  Please see last page of form for CLIA Specialty and Subspecialty Information.
  CLIA Number: _________________________________
  Laboratory Name: _______________________________
  Address/Location: _______________________________
  City, State, Zip: _________________________________
  Effective Patient Testing Date:
  High Complexity Test/Analyte(s) Performed:
  Instrument(s)/Methodology:

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Accreditation
Laboratory

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Is laboratory performing other high complex testing, under the applicable specialty/sub-specialty?
Proficiency Test Provider(s), if applicable: ____________________________________________
Estimated Annual Test Volume: ____________________________________________________

- **Change in number of locations associated with an existing Certificate of Accreditation**
  - CLIA Number: ________________________________________________________________
  - Specialty/Service: ____________________________________________________________
  - New number of locations: ____________________________________________________

- **Site (laboratory) Address/Name Change**
  - CLIA Number: ________________________________________________________________
  - New Name: _________________________________________________________________
  - New Address: ________________________________________________________________
  - City, State, Zip: _____________________________________________________________
  - Effective Date: ______________________________________________________________

- **Ownership Change**
  - CLIA Number: ________________________________________________________________
  - Current Owner: ______________________________________________________________
  - New Owner: _________________________________________________________________
  - Effective Date: ______________________________________________________________

- **Laboratory Director Change (as identified on CLIA certificate)**
  Note: Please be sure to update the Lab Director via your Lab Central Connect site. Lab Central Connect is available under the Continuous Compliance Tools section of your secure Joint Commission Extranet site.

Please mail or fax your updates within 30 days of the change to your Account Executive. Your Account Executive's name is available on your secure extranet site.

The Joint Commission
Attn: Accreditation and Certification Operations/Name of Account Executive
One Renaissance Boulevard
Oakbrook Terrace, IL 60181

For office use only:
Date Updated: ________________________
Initials: ______________________________
Acknowledged Date: ___________________
Initials: ______________________________
Proficiency Testing Enrollment Checklist

CLIA regulations require that your laboratory enroll in a Centers for Medicare and Medicaid Services (CMS) approved proficiency testing (PT) program for all regulated tests that you perform. Annually, the Joint Commission requires you to submit documentation attesting to your organization’s enrollment in an approved PT program for each CLIA certificate surveyed by the Joint Commission under which moderate or high complexity tests of all regulated tests are performed.

To assist your organization in ensuring compliance with CLIA regulations and Joint Commission accreditation requirements for each CLIA certificate requiring enrollment in a CMS approved PT program, you should review each of your CLIA certificates and complete a Proficiency Testing Enrollment Worksheet for each CLIA certificate surveyed by the Joint Commission before submitting your required Attestation Form to the Joint Commission.

1. Identify all CLIA certificates surveyed by the Joint Commission.

2. For each CLIA certificate surveyed by the Joint Commission, determine if moderate or high complexity testing is performed under that certificate.

3. For each CLIA certificate surveyed by the Joint Commission under which moderate or high complexity testing is performed, use the Proficiency Testing Enrollment Worksheet, determine if the moderate and/or high complexity test(s) performed are regulated analytes that require enrollment in proficiency testing.

4. Complete one copy of the Proficiency Testing Enrollment Worksheet for each CLIA certificate that is accredited by the Joint Commission and is registered to perform moderate and/or high complexity testing of regulated analytes that require proficiency testing.

5. Place a checkmark by each regulated analyte that your laboratory is performing under that CLIA number that requires proficiency testing.

6. Ensure that each regulated analyte is enrolled in a CMS approved proficiency testing program for the coming year. Document the name of the proficiency testing provider for each regulated analyte in the column labeled "Approved CMS Proficiency Test Provider." Record the year in the column labeled "Enrolled For The Year Of ____" and, then, place a checkmark in the associated field in the column for each relevant regulated analyte. Obtain the signature of the Laboratory Director.

7. Once you have completed a review of all your CLIA certificates that are accredited by the Joint Commission that are registered to perform moderate and/or high complexity testing of regulated analytes that require proficiency testing and verified enrollment with a CMS approved PT provider, log on to your organization’s secure Joint Commission Connect extranet site. A link to the attestation form is on the extranet home page in the section for Continuous Compliance Tools. Select the link to access and complete the form. Please make note of your organization’s Joint Commission ID# as you will need to enter this number on the attestation form.

8. Print a copy of the form prior to submission for your records.

Note: Due to the volume of forms received, the Joint Commission will not be able to respond to individual inquiries for verification of receipt of the Attestation Form. Once all Attestation Forms are received and recorded, Joint Commission staff will contact your organization should we fail to receive the form from your organization based on information currently on file in our database.

9. Retain your original completed Attestation Form along with your completed Proficiency Testing Enrollment Worksheets. DO NOT FORWARD the Proficiency Testing Enrollment Worksheets to the Joint Commission. Please be prepared to make original source verification of proficiency test enrollment available to Joint Commission surveyors at the time of survey.
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10. A confirmation e-mail will be sent to your Laboratory Accreditation Primary Contact and posted to your Joint Commission Extranet site in the Official Email section under Quicklinks within 7 – 10 business days.
Proficiency Testing Enrollment Worksheet

The proficiency test worksheet has been developed to assist you in your efforts in determining required enrollment in proficiency testing. **DO NOT** send the completed *Proficiency Testing Enrollment Worksheet* to The Joint Commission.

**DO NOT** complete the proficiency test worksheet for waived testing methods or non-regulated analytes.

CLIA Certificate Number _____D_______________

<table>
<thead>
<tr>
<th>Specialty/Subspecialty</th>
<th>Analyte</th>
<th>Approved CMS Proficiency Test Provider</th>
<th>Enrolled for the year of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiology</td>
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<tr>
<td>Bacteriology</td>
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<td>vAerobic/anaerobic culture and identification</td>
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<tr>
<td>Antibiotic susceptibility testing</td>
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<td>Direct antigen detection</td>
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<tr>
<td>Includes, but not limited to: C. Difficile, Chlamydia, H. Pylori</td>
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<td>Gram stain</td>
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<td>Mycobacteriology</td>
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<td>Acid-fast stains</td>
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<td>Mycobacterial identification</td>
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<td>Mycobacteriology susceptibility testing</td>
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<td>Mycology</td>
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<tr>
<td>Antigen detection</td>
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<tr>
<td>Culture and identification</td>
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<tr>
<td>Parasitology</td>
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<td>Presence or absence of parasites</td>
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<tr>
<td>Identification of parasites</td>
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<tr>
<td>Virology</td>
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<tr>
<td>Viral antigen detection</td>
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<tr>
<td>Includes, but not limited to: RSV, Influenza A/B</td>
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<tr>
<td>Viral antibody is not categorized as virology</td>
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<tr>
<td>Isolation and identification</td>
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## Diagnostic Immunology

<table>
<thead>
<tr>
<th>Syphilis Serology</th>
<th>RPR and VDRL</th>
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<tbody>
<tr>
<td>General Immunology</td>
<td></td>
</tr>
<tr>
<td>Alpha-1 antitrypsin</td>
<td></td>
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<tr>
<td>Alpha-fetoprotein (tumor marker)</td>
<td></td>
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<tr>
<td>Antinuclear antibody</td>
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<tr>
<td>Anti-human immunodeficiency virus (HIV)</td>
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<tr>
<td>Antistreptolysin O</td>
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<tr>
<td>Complement C3</td>
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<tr>
<td>Complement C4</td>
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</tr>
<tr>
<td>Hepatitis B surface antigen</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C core antibody</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B e antigen</td>
<td></td>
</tr>
<tr>
<td>Immunoglobulins IgA</td>
<td></td>
</tr>
<tr>
<td>Immunoglobulins IgG</td>
<td></td>
</tr>
<tr>
<td>Immunoglobulins IgM</td>
<td></td>
</tr>
<tr>
<td>Immunoglobulins IgE</td>
<td></td>
</tr>
<tr>
<td>Infectious mononucleosis</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid factor</td>
<td></td>
</tr>
<tr>
<td>Rubella</td>
<td></td>
</tr>
</tbody>
</table>

## Hematology

| Cell identification |              |
| Automated Differential |              |
| Erythrocyte count |              |
| Hematocrit |              |
| Hemoglobin |              |
| Leukocyte count |              |
| Platelet count |              |
| Fibrinogen |              |
| Partial thromboplastin time |              |
| Prothrombin time |              |
| White blood cell differential |              |

## Immunohematology

| ABO group (excluding subgroups) |              |
| D and RH typing |              |
| Unexpected antibody detection |              |
| Compatibility testing |              |
| Antibody identification |              |
### Chemistry

Routine chemistry (serum, plasma, or blood)

<table>
<thead>
<tr>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine aminotransferase (ALT/SGPT)</td>
</tr>
<tr>
<td>Albumin</td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
</tr>
<tr>
<td>Amylase</td>
</tr>
<tr>
<td>Aspartate aminotransferase (AST/SGOT)</td>
</tr>
<tr>
<td>Bilirubin, total</td>
</tr>
<tr>
<td>Blood gases pH</td>
</tr>
<tr>
<td>Blood gases pCO2</td>
</tr>
<tr>
<td>Blood gases pO2</td>
</tr>
<tr>
<td>Calcium, total</td>
</tr>
<tr>
<td>Chloride</td>
</tr>
<tr>
<td>Cholesterol, high density lipoprotein</td>
</tr>
<tr>
<td>Cholesterol, total</td>
</tr>
<tr>
<td>Creatine kinase</td>
</tr>
<tr>
<td>Creatine kinase, isoenzymes (CK-MB)</td>
</tr>
<tr>
<td>Creatinine</td>
</tr>
<tr>
<td>Glucose</td>
</tr>
<tr>
<td>Iron, total</td>
</tr>
<tr>
<td>Lactate, dehydrogenase (LDH)</td>
</tr>
<tr>
<td>LDH isoenzymes</td>
</tr>
<tr>
<td>Magnesium</td>
</tr>
<tr>
<td>Potassium</td>
</tr>
<tr>
<td>Sodium</td>
</tr>
<tr>
<td>Total protein</td>
</tr>
<tr>
<td>Triglyceride</td>
</tr>
<tr>
<td>Urea nitrogen</td>
</tr>
<tr>
<td>Uric acid</td>
</tr>
</tbody>
</table>

### Endocrinology

(serum, blood, or plasma)

<table>
<thead>
<tr>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortisol</td>
</tr>
<tr>
<td>Free thyroxine</td>
</tr>
<tr>
<td>Human chorionic gonadotropin</td>
</tr>
<tr>
<td>Thyroid-stimulating hormone</td>
</tr>
<tr>
<td>T3 uptake</td>
</tr>
<tr>
<td>Thyroxine, total</td>
</tr>
<tr>
<td>Triiodothyronine</td>
</tr>
</tbody>
</table>
## Excellence in Laboratory Accreditation

<table>
<thead>
<tr>
<th>Toxicology (serum, plasma, or blood)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol (blood)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood lead</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digoxin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethosuximide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenobarbital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenytoin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primidone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procainamide (and metabolite)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quinidine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobramycin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theophylline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valproic acid</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GYN Cytology</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Director Signature</td>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>

---

**The Joint Commission Accreditation Laboratory**
Survey Planning and Readiness Notes:

1. Please review the following Laboratory Survey Activity List which has been developed to assist you in preparing for your survey. The list includes the potential survey activities that can occur on a Laboratory survey, suggested duration, and suggested timing for these activities. Timing is dependent upon the size and scope of the laboratory services provided. This information is provided so that your organization may begin to identify the participants that need to be involved in the survey. Included in the activity list is a column for your use to record participant names, possible meeting locations, or any other notes.

2. If your laboratory is being surveyed by The Joint Commission at the same time as another program in your organization, please consider including the following in your survey readiness plans:
   - Arrangements to have a laboratory representative available in-person or by phone for the Opening Conference and Orientation to the Organization session.

Please plan to collaborate with your surveyor(s) to confirm the best day and time for specific survey activities to take place.

<table>
<thead>
<tr>
<th>Activity Name</th>
<th>Suggested Duration of Activity</th>
<th>Suggested Scheduling of Activity</th>
<th>Key Organization Participants (Refer to Survey Activity Guide for more info.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening Conference</td>
<td>15 minutes</td>
<td>1st day, as early as possible</td>
<td></td>
</tr>
<tr>
<td>Orientation to Organization</td>
<td>30 - 45 minutes</td>
<td>1st day, as early as possible</td>
<td></td>
</tr>
<tr>
<td>Surveyor Planning Initial</td>
<td>30-45 minutes</td>
<td>1st day, as early as possible</td>
<td></td>
</tr>
<tr>
<td>Tracer Activity</td>
<td>60-120 minutes</td>
<td>Tracer activity occurs throughout the survey; the amount of tracer activity varies by organization</td>
<td></td>
</tr>
<tr>
<td>Lunch</td>
<td>30 minutes</td>
<td>At a time negotiated with the organization</td>
<td></td>
</tr>
<tr>
<td>Issue Resolution</td>
<td>30 minutes</td>
<td>End of each day except last; can be scheduled at other times as necessary</td>
<td></td>
</tr>
<tr>
<td>Team Meeting/Surveyor Planning</td>
<td>30 minutes</td>
<td>Mid-day and/or end of each day except last when more than one surveyor on site</td>
<td></td>
</tr>
<tr>
<td>Daily Briefing</td>
<td>15-30 minutes</td>
<td>Start of each survey day except the first day; can be scheduled at other times as necessary</td>
<td></td>
</tr>
<tr>
<td>Competence Assessment</td>
<td>60 minutes</td>
<td>After some tracer activity has occurred; often times will be addressed during tracer activity</td>
<td></td>
</tr>
<tr>
<td>Proficiency Testing/Validation/Performance Improvement Data Review</td>
<td>90-120 minutes</td>
<td>1st day, must occur immediately after Regulatory Review</td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Activity Name</th>
<th>Suggested Duration of Activity</th>
<th>Suggested Scheduling of Activity</th>
<th>Key Organization Participants (Refer to Survey Activity Guide for more info.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Review</td>
<td>30 minutes</td>
<td>1st day; must occur before or just after Surveyor Planning Session</td>
<td></td>
</tr>
<tr>
<td>Report Preparation</td>
<td>60-90 minutes</td>
<td>Last day of survey</td>
<td></td>
</tr>
<tr>
<td>CEO Exit Briefing</td>
<td>15 minutes</td>
<td>Last day of survey</td>
<td></td>
</tr>
<tr>
<td>Organization Exit Conference</td>
<td>30 minutes</td>
<td>Last day, final activity of survey</td>
<td></td>
</tr>
</tbody>
</table>

Contact your Account Executive with any questions related to this information.
On behalf of the organization named above,

I hereby attest that, in consultation with the responsible laboratory director(s), a thorough review and assessment of all CLIA Certificates has been completed, and each laboratory, as appropriate, is enrolled with a Centers for Medicare and Medicaid Services (CMS) approved Proficiency Testing provider and participates in a Proficiency Testing program that meets regulatory requirements set forth under the Clinical Laboratory Improvement Act with respect to the variety and frequency of testing for the period January 1, 2013 to December 31, 2013.

I further attest that, should my organization acquire a new CLIA Number and/or perform regulated testing not previously covered by this document, my organization will enroll and participate with a Centers for Medicare and Medicaid Services (CMS) approved Proficiency Testing provider for the next scheduled proficiency testing event.

Furthermore, I agree to notify the Joint Commission in writing with information regarding the new CLIA Number and/or the regulated testing not previously covered by this document, and the name of the approved Proficiency Testing provider selected, within 30 days after acquiring a new CLIA Number and/or initiating regulated testing.

Primary Contact or CEO: ________________________________
Title: ________________________________
Phone Number: ________________________________

Please print this page prior to submission for your organization records.
CLIA Specialty and Subspecialty Information

- Histocompatibility - Transplant
- Histocompatibility - Nontransplant
- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology
- Syphilis Serology
- General Immunology
- Routine Chemistry
- Urinalysis
- Endocrinology
- Toxicology
- Hematology (includes coagulation and andrology)
- Immunohematology
  - ABO Group and RH Group
  - Antibody Detection (transfusion)
  - Antibody Detection (nontransfusion)
  - Antibody Identification
  - Compatibility Testing
- Histopathology
- Oral Pathology
- Cytology
- Radiobioassay
- Clinical Cytogenetics
GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.

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

- Testing for allergens should be counted as one test per individual allergen.

- For **chemistry** profiles, each individual analyte is counted separately.

- For **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.

- For **complete blood counts**, each measured individual analyte that is ordered and reported is counted separately. Differentials are counted as one test.

- Do not count calculations (e.g., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays.

- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.

- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.

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

- For **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.
Investigation Form

Purpose: This form is provided as a reference tool for laboratories to investigate the possible causes of unsatisfactory proficiency testing results. Not all errors can be identified with one particular tool. Laboratories should consider the unique factors for each test system and expand its investigation when indicated.

1. General
   A. Did more than one challenge in this event fail? □ Yes □ No
   B. Did more than one analyte fail? □ Yes □ No
   C. Are there previous trends/unacceptable results for this test? □ Yes □ No
   D. Do the SDIs show a bias in the current event or from event to event? □ Yes □ No
   E. Was there low consensus for the analyte or sample? □ Yes □ No
   F. Were there <10 participants in the event peer group? □ Yes □ No
   G. Provide the scores from the three prior events (most recent first):
      | Year | Event | Score |
      |------|-------|-------|
      |      |       |       |
      |      |       |       |
      |      |       |       |

2. Administrative
   A. Was the PT kit ordered on time? □ Yes □ No
   B. Were results submitted to the PT provider? □ Yes □ No
   C. Were results submitted to the PT provider on time? □ Yes □ No
   D. Did the PT provider receive the results? □ Yes □ No
   E. Was the PT provider instructed to report the results to CMS? □ Yes □ No
   F. Other___________________________________________

3. Clerical
   A. Were results transcribed correctly? □ Yes □ No
   B. Was the correct method code selected? □ Yes □ No
   C. Was the correct reagent code selected? □ Yes □ No
      □ N/A
   D. Was the correct instrument code selected? □ Yes □ No
      □ N/A
   E. Was unit conversion performed correctly, if applicable? □ Yes □ No
      □ N/A
   F. Other___________________________________________

4. Methodological & Technical (problems attributable to either the test system or laboratory personnel actions)
   A. Problem with proficiency testing material
      1. Was the kit received without delays in transport? □ Yes □ No
      2. Did the kit arrive at the appropriate temperature? □ Yes □ No
      3. Were proper storage conditions maintained? □ Yes □ No
      4. Were the samples prepared per the PT provider instructions¹? □ Yes □ No
      5. Other___________________________________________
   B. Instrument maintenance
      1. Were there any problems with routine instrument maintenance²? □ Yes □ No
         □ N/A
      2. Was there any unscheduled maintenance? □ Yes □ No

¹ Prepared at recommended temperatures with proper reconstitution volumes, diluents, etc.
² At the manufacturer suggested intervals and according to laboratory policy.
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☐ N/A
3. Was there service or repair by a service rep? ☐ Yes ☐ No
☐ N/A
4. Were any major parts replaced? ☐ Yes ☐ No
☐ N/A
5. Other ______________________________________

C. Calibration or calibration verification
1. Did the instrument have successful calibrations or calibration verifications? ☐ Yes ☐ No
☐ N/A
2. Was calibration or calibration verification performed when it was due3? ☐ Yes ☐ No
3. Date of last calibration before PT testing: ___________
☐ N/A
4. Date of last calibration verification before PT testing: ___________
☐ N/A
5. Was PT result within the linear range of instrument? ☐ Yes ☐ No
6. Other _______________________________________

D. Quality control and reagents
1. Was there unacceptable QC on the day of PT testing? ☐ Yes ☐ No
2. Was there unacceptable QC during the month previous to the day of testing? ☐ Yes ☐ No
3. Was there unacceptable QC during the month following the day of testing? ☐ Yes ☐ No
4. Were any shifts or trends identified? ☐ Yes ☐ No
5. Date of last lot change in QC material before PT testing: ___________
☐ N/A
6. Date of last lot change in reagents before PT testing: ___________
☐ N/A

E. Microbiology specific
1. Was QC acceptable for:
   a. the media used? ☐ Yes ☐ No
   ☐ N/A
   b. the identification system? ☐ Yes ☐ No
   ☐ N/A
c. other biochemical testing? ☐ Yes ☐ No
   ☐ N/A
d. susceptibility testing? ☐ Yes ☐ No
   ☐ N/A
e. stains used? ☐ Yes ☐ No
   ☐ N/A
2. Was the correct culture media selected for inoculation? ☐ Yes ☐ No
☐ N/A
3. Were the growth conditions acceptable (temp, CO₂, humidity)? ☐ Yes ☐ No
☐ N/A
4. Were the cultures mixed? ☐ Yes ☐ No
   ☐ N/A
5. Were adequate isolation techniques used by the personnel? ☐ Yes ☐ No
☐ N/A
6. Was the McFarland standard acceptable4? ☐ Yes ☐ No
☐ N/A
7. Did the organism demonstrate a typical biochemical reaction pattern? ☐ Yes ☐ No
☐ N/A
8. Were purity plates OK? ☐ Yes ☐ No

3 As required by the manufacturer and at least every six months.
4 Reference standards not expired, correct standard dilution was used, pipette delivered correct volumes, etc.
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☐ N/A
9. Did the lyophilized organism demonstrate typical characteristics\(^5\)? ☐ Yes ☐ No
☐ N/A

F. Immunohematology specific
   1. Was there a weak reaction? ☐ Yes ☐ No
   ☐ N/A
   2. Was antibody detectable, but not identifiable? ☐ Yes ☐ No
   ☐ N/A
   3. Was there interference caused by a positive direct antiglobulin test? ☐ Yes ☐ No
   ☐ N/A

G. Repeat testing, if performed
   1. Repeat testing result: _______________________________ ☐ Specimen
   not available
   2. Is result now acceptable? ☐ Yes ☐ No
   ☐ N/A

5. Evaluation of Patient Results
   A. Determine if patient results could have been affected by the error since the last successful PT event.
   B. If results could be affected, conduct an evaluation for potential adverse patient outcomes.
   C. If the potential for adverse patient outcomes is identified, notify the patient’s physicians, per 42 CFR 493.1282.

6. Plan of Action Review
   A. Are policies and procedures written in a manner to prevent recurrence? ☐ Yes ☐ No
   B. Are systems and processes designed to prevent recurrence? ☐ Yes ☐ No
   C. Are personnel trained and competent on the above (items 6A & 6B)? ☐ Yes ☐ No
   D. Is there ongoing oversight in place to prevent recurrence? ☐ Yes ☐ No

<table>
<thead>
<tr>
<th>Testing personnel:</th>
<th></th>
</tr>
</thead>
</table>

Signature of Laboratory Director / Date _____________________ Signature of General Supervisor / Date _____________________

Retain this record for at least two years.

---

\(^5\) Lyophilized organisms sometimes lose their characteristics and require multiple culture passes to regain expression.