

COLA LABORATORY

Accreditation Manual



JUNE 2013

COLA[®]

Accreditation Education Innovation

Fast Answers

You can use this Manual to help you find answers quickly.

COLA phone number: 800-981-9883, Monday through Friday, 9 a.m. to 5 p.m. EST; Email address: info@cola.org

COLA Educational Products:
www.labuniversity.org

Table of Contents, page 3

Helpful tips, learning points, highlight boxes, reminders included throughout this Manual

Benefits of COLA Accreditation

- Improved patient safety
- More accurate laboratory results
- Compliance with regulatory standards
- Evidence of quality laboratory practices
- More efficient, productive laboratory operations
- Improved customer satisfaction
- Ongoing monitoring of proficiency testing

Professional External Assessment Program Focused on Laboratory Quality and Performance Excellence

The purpose of this Accreditation Manual is to provide you with the information and help you need to successfully participate in COLA's laboratory accreditation program and become a high performing medical laboratory.

This Manual will help you understand how the COLA accreditation process works, familiarize you with the standards and responsibilities a laboratory must meet to ensure compliance, and describe how COLA and its staff of professionals can support you as you strive for accreditation.

On the following pages you will find a detailed but easy-to-follow description of the COLA accreditation program, including:

- The sequence of steps required to complete COLA accreditation and what's involved
- The relationship between COLA, CLIA, and regulatory bodies such as CMS and state agencies
- A description of the roles of laboratory staff in supporting the accreditation process and important actions you need to take
- COLA Criteria for Quality Laboratory Performance
- Comprehensive information about the many COLA educational opportunities available to enhance staff knowledge and skills
- An overview of the resources available to answer your questions and help you develop a compliance strategy that works for your organization.



Accreditation Education Innovation

Summary of Revisions

Additions

Criteria Groupings LDR and WAV

Deletions

None

Revisions

ORG 16, 17, 18; PER 2, 4, 5; PT 1, 7, 9; MA 15, 17; VER 5, 6, 7, 8, 9, 10, 11; QC1, 8, 23, 30; CO2; C5, 6; U2; SU4; PST4, 25, 26, 27, QA 1; TS 5, 45, 103;

I. Introduction to Accreditation

Forward: Message from COLA CEO.....	5
COLA Accreditation – An Introduction and Overview.....	6
Laboratories Eligible for COLA Accreditation.....	6
The VALUE of COLA Accreditation.....	7
Here’s How to Contact COLA and Get Help Fast.....	8
COLA, Regulatory Compliance, and Your Laboratory.....	9

II. COLA Accreditation: How it Works, What to Do

The Road to Accreditation: Important Facts You Need to Know.....	18
Step 1: Enrollment and Completion of Forms.....	20
Step 2: Completing the Self-Assessment.....	21
Step 3: On-site Survey.....	22
Step 4: Post-Survey and Corrective Action.....	27
Step 5: Accreditation.....	30

III. COLA Criteria for Quality Laboratory Performance

Overview: COLA Criteria for Quality Laboratory Performance and Self-Assessment Question.....	37
The Criteria and Self-Assessment Follow the Path of Workflow.....	37
About the Self-Assessment Questions And Answer Sheet.....	38
Essential (E) vs. Required (R) Criteria.....	38
The Criteria Cover 17 Main Evaluation Groupings In the Laboratory Path of Workflow.....	39
Understanding the Criteria and Completing The Self-Assessment: Helpful Information By Evaluation Grouping.....	40
Transfusion Services Criteria.....	140

IV. Educational Resources and Support

LabUniversity® On-Line Continuing Education.....	159
Lab Director CME Program for Physicians.....	160
Symposium for Clinical Laboratories™.....	160
Educational Publications and Products.....	160
Continuous Quality Program.....	160
Other Internet Resources.....	161

V. Appendix.....162

Accreditation Quick Look: What’s Involved

You complete a series of steps on your road to accreditation:

INFORMATION GATHERING AND REPORTING...

- Upfront, you supply COLA with information about your laboratory
- You become familiar with the steps in accreditation and responsibilities in the process
- You conduct a detailed self-assessment of your laboratory operations, reporting the data to COLA
- You make sure you meet other requirements of state and federal agencies
- You have proficiency testing data released to COLA and respond to notices of unsuccessful performance

ON-SITE SURVEY...

- COLA conducts an on-site survey to assess your laboratory’s compliance

FEEDBACK AND IMPROVEMENT...

- COLA experts provide you with feedback on your laboratory’s operation, including identification of noncompliances that need to be corrected
- COLA experts provide you with experienced guidance in the correction of noncompliant criteria
- Your laboratory addresses areas of noncompliance and takes corrective action
- You provide documented proof of improvements to COLA

CONGRATULATIONS! ACCREDITATION...

When COLA has determined that you are compliant with all of its criteria, your laboratory is granted accreditation.

Helpful Tips! How to use this manual...

As you read through this Manual, look for icons like the ones described below, as well as the many quick tip features you'll see, because they provide helpful hints or alert you to information that is important for you to know.



IN THIS SECTION – The first page of each section in this Manual has its own “In This Section” table of contents identified by the icon. The Table of Contents can be a useful guide for finding information quickly.



ACTION REQUIRED – These brief items will point out important actions your laboratory needs to take as part of the accreditation process.



QUICK TIPS – Quick Tips are located throughout the text and provide helpful information and reminders, or things to think about.



LEARNING POINTS – This pencil icon identifies key learning points as you strive to educate yourself and your staff about accreditation.



AT A GLANCE – Look for this icon for a quick summary of key points in the section.

This Manual provides all the detailed information you need to become accredited with COLA. But to help you make efficient use of your time, we have included a mini table of contents for each major section, complemented by easy-to-follow flow charts, quick tips, highlight boxes, and key learning points throughout the text to help you quickly grasp what's most important for your laboratory to know and do during the accreditation process.

The contents of the Accreditation Manual are organized into a logical path that consists of the following sections:

Section I: Introduction to Accreditation

Here, the COLA CEO introduces you to the unique and value-added aspects of COLA accreditation, accompanied by an overview of COLA, its range of services, and its historical involvement in accreditation. In this section, you'll also enhance your understanding of the benefits of accreditation, the authority of COLA as an accreditation organization in the CLIA regulatory process, and the responsibilities your laboratory and COLA are required to meet.

Section II: COLA Accreditation, Step-by-Step: How it Works, What You Do

COLA has developed a multi-step process to complete accreditation. This section of the Manual walks you through the steps on the road to accreditation. Here, you will find all the information you need to know to get started with accreditation and what your laboratory and your staff need to do to support the process.

Section III: COLA Criteria for Quality Laboratory Performance

In this section, you'll learn about all the criteria your laboratory must meet to become accredited. The Self-Assessment introduces you to the COLA criteria and is an integral part of the COLA accreditation process.

Section IV: Educational Resources and Support

Educational resources support and assistance are COLA's strengths. Here you'll learn about the wide array of resources and tools available through COLA that can help build your knowledge.

Section V: Appendix

Here you'll find reference and support materials related to subjects covered in the content of the Manual.



IN THIS SECTION

Foreword: Message from COLA CEO	5
COLA Accreditation – An Introduction and Overview	6
Laboratories Eligible for COLA Accreditation	6
The VALUE of COLA Accreditation	7
Here’s How to Contact COLA and Get Help Fast	8
COLA, Regulatory Compliance, and Your Laboratory	9

FOREWORD: MESSAGE FROM COLA CEO By Douglas A. Beigel, Chief Executive Officer

COLA Accreditation: Built on a Foundation of Education and Partnership with the Medical Community

Welcome and congratulations on your decision to participate in the COLA Laboratory Accreditation Program.

Laboratory professionals have found COLA’s accreditation program to be an excellent quality improvement and educational development process, as well as an effective and convenient way to meet the laboratory regulations mandated by the Clinical Laboratory Improvement Amendments (CLIA) of 1988. COLA standards have been developed by clinical laboratory professionals and are based on practical, proven methods and accepted good laboratory practices that meet regulatory requirements.

COLA’s commitment to excellence in accreditation is built on a foundation of education and partnership with the medical community. One of the truly unique aspects of the COLA accreditation program is its focus on education. You’ll grow your knowledge of laboratory processes through COLA’s accreditation program and can fulfill your learning and training needs with COLA educational products, including on-line courses offered through LabUniversity®.

We’ve made our accreditation process as straightforward as possible – preparing and educating you step-by-step, always using clearly understood requirements and working with you to develop a compliance strategy that works for your organization.

Another important feature of COLA accreditation is its emphasis on partnership. Accreditation success comes with teamwork, and as you travel along the road to accreditation, COLA will provide guidance and support to you every step of the way. Our staff is knowledgeable, accessible, approachable, and readily available to help you. You’ll receive guidance and feedback from COLA staff that will help you gauge your progress, offering suggestions for improvement and achievement of full compliance.

I encourage you to take full advantage of this manual and the many other learning tools and educational opportunities COLA will make available to you and your staff during the accreditation process. We provide the tools and education to help laboratories succeed. But success will depend on the effort you and your staff put into the accreditation process.

With approximately 60-70 percent of all diagnostic decisions influenced by work done in laboratories (Forsman RW, Clin Chem 1996: 42:813-816), you play a critical role in the healthcare system. A number of factors – including implementation of the Affordable Healthcare Act, future regulation of waived testing, and the rise of new healthcare delivery models such as Accountable Care Organizations and Patient Centered Medical Homes – will help usher in a period of rapid change for both labs and the healthcare system. COLA stands ready to assist you as you adapt to this transforming landscape.

We have attempted to make this Manual as comprehensive as possible. However, if you have questions about the accreditation process or our services, contact COLA at (800) 981-9883.

Good luck on your journey to accreditation!

COLA Accreditation – An Introduction and Overview

The COLA accreditation program is educationally oriented. COLA's mission is to help physicians, clinical laboratory professionals, and healthcare staff to operate accurate and efficient laboratories. By earning accreditation through COLA, laboratories also meet federal CLIA requirements. Laboratories are also required to meet applicable state requirements.

COLA's roots run to the heart of the medical community. COLA was incorporated as a non-profit organization in 1988, and is sponsored by the American Academy of Family Physicians, the American College of Physicians, and the American Medical Association. COLA's laboratory accreditation program is endorsed by 29 national and state medical associations, including the American Academy of Clinical Endocrinologists, the American Academy of Neurology, and the American College of Rheumatologists.

Because COLA believes strongly that the lab director's involvement in daily operations is vital to the success of the lab, it is COLA's policy that all written correspondence is addressed to the laboratory director.

Laboratories Eligible for COLA Accreditation

COLA offers clinical laboratory education and accreditation to laboratories of all types and sizes. We accredit the following types of laboratories:

- *Office laboratories* – These are defined as a clinical laboratory used by a fully licensed physician to test specimens collected primarily from patients of the practice. They are usually located at the physician's principal site of care. Where the laboratory is part of a group practice, HMO, clinic, residency program, Indian Health Service clinic, public health clinic (or similar patient care facility), student health service clinic, or other practice arrangement, COLA expects that a full licensed physician be responsible for the operation of the laboratory in accordance with COLA standards and in the best interests of the patients served by the laboratory.
- *Point of care laboratories* – These include ancillary testing sites, ambulatory surgery clinics, community clinics, home health agencies, hospices, mobile units, skilled nursing facilities, renal dialysis units and similar facilities.
- *Mobile laboratories* – These are a fleet of mobile laboratories accredited as a single unit when all units perform the same tests and use the same instrumentation for a limited or small number of specialty analytes.
- *Community hospital laboratories* – These are community hospital laboratories without surgical pathology or cytology performed on-site.
- *Full service hospital laboratories* – These are hospital-based laboratories that operate on a 24-hour basis, providing inpatient and often outpatient laboratory services that may include transfusion services, usually under the direction of a pathologist. COLA does not accredit the specialty of Pathology.
- *Reference laboratories* – These are commercial laboratories that provide clinical laboratory testing for other laboratories and clients. Reference laboratories perform routine testing and perform tests that are highly complex and esoteric in nature, low volume, or cost inefficient for other laboratories to perform.

Limitations of Eligibility

An individual who has owned or operated a laboratory which has had its CLIA certificate revoked within the past 24 months may not own or operate a laboratory accredited by COLA.

CMS-Approved Specialties

Your laboratory must test only in those specialties for which there are accredited by COLA or use a CLIA-approved accreditation organization or state survey agency for those specialties for which COLA is not approved by CLIA to accredit. COLA is approved by the Centers for Medicare and Medicaid Services (CMS) to accredit laboratories performing tests in the following specialties:

- Chemistry, including endocrinology, toxicology, urinalysis, and methods utilizing radioimmunoassay (RIA)
- Hematology, including coagulation
- Microbiology, including bacteriology, mycobacteriology, mycology, parasitology, and virology
- Diagnostic Immunology, including general immunology and syphilis serology
- Immunohematology and transfusion services, compatibility testing The COLA accreditation program does not at this time accredit testing in such specialties as:
- Pathology, including cytology, histopathology, dermatopathology, and oral pathology
- Histocompatibility
- Cytogenetics
- Forensic drug testing
- Radiobioassay

The VALUE of COLA Accreditation

When you become an accredited laboratory, you have positioned your laboratory to realize the following benefits:

1. **More Accurate Laboratory Results and Improved Patient Safety...** Through adherence to COLA standards, laboratory testing errors are reduced; weaknesses in workflow, processes, and procedures are addressed; and overall operations are aligned with accepted practices.
2. **Compliance with Regulatory Standards...** Through COLA accreditation, your laboratory is recognized by the Centers for Medicare and Medicaid Services (CMS) as meeting the regulatory requirements of CLIA.
3. **More Efficient and Productive Operations...** The accreditation process, including completion of the Self-Assessment educational tool, facilitates a thorough examination of the laboratory's entire operation. Corrective action you take based on your own assessment and COLA recommendations reduces the potential for error, minimizes repeat work, and relieves the organization of unnecessary tasks.
4. **Improved Customer Satisfaction...** The higher quality and greater consistency that emerge from a more efficient workflow lead to increase trust and confidence with the public and with the healthcare community.
5. **COLAcentral®...** COLA customers have access to the tools needed to run an efficient laboratory and improve patient care. Our client portal website is designed to provide a resource where laboratory professionals can update their lab profile, view communications, see survey results, prepare for upcoming surveys and receive support for a wide range of laboratory needs. Go to www.colacentral.com to register!

Have a Question About Accreditation? Need More Information? Here's How to Contact COLA and Get Help Fast...

COLA's experts are readily available to help you. Never hesitate to contact COLA for information and help on accreditation or any other COLA service.

By internet:

www.cola.org

www.colacentral.com

LabUniversity®:

www.labuniversity.org

Obtain information about on-line training courses that can enhance your laboratory knowledge and provide continuing education credit.

By E-Mail:

info@cola.org

Write us with your specific accreditation questions, which will be directed to members of the COLA staff.

By Phone:

Contact COLA at 800-981-9883. Ask COLA staff about accreditation, educational products, and laboratory related issues.

By Fax:

410-381-8611

By Regular Mail:

Write to us at Accreditation Division, COLA, 9881 Broken Land Parkway Suite 200, Columbia, MD 21046

COLA, Regulatory Compliance, and Your Laboratory

Background

When Congress passed the Clinical Laboratory Improvement Amendments of 1988 (CLIA), a new era of laboratory regulation was implemented. CLIA established quality standards for all diagnostic laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results.

Management and operation of the CLIA program was assigned to the Centers for Medicare and Medicaid Services (CMS), a branch of the U.S. Department of Health and Human Services. Today, CMS regulates all laboratory testing “for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of humans.”

How COLA Operates Within the Regulatory Structure

A landmark moment in COLA history was the decision by federal rule makers to allow private accrediting organizations like COLA to work within the regulatory structure as an alternative to direct federal government oversight and inspection by CMS.

As a result of this action, COLA was approved by CMS as a private, non-profit accrediting organization for CLIA purposes. Thus, when a laboratory applies to COLA and is granted accreditation, CMS recognizes the lab as meeting CLIA requirements.

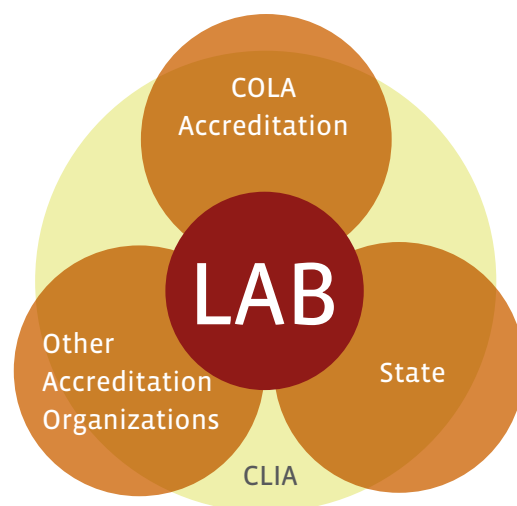


Key Terms in Regulation

CLIA – Clinical Laboratory Improvement Amendments of 1988 established quality standards for all laboratory testing in the United States.

CMS – Centers for Medicare and Medicaid Services. CMS regulates laboratory testing “for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment or the assessment of health for humans.”

Interrelationships between Lab, CLIA & COLA





What Accreditation Means...

When a laboratory is granted COLA accreditation, CMS recognizes the COLA- accredited lab as meeting all CLIA requirements.

However, it is important to note that laboratories remain subject to federal validation and complaint investigation inspections performed by any federal, state, public agency, or non-profit service organization under an agreement with the Department of Health and Human Services.

Some COLA standards vary from federal CLIA standards, while others are identical. The important point to know is that COLA accredited laboratories are required to meet all COLA standards, and by doing so they meet all CLIA standards.

COLA Standards in Relation to CLIA

COLA standards were developed by physicians, clinical laboratory scientists, and other clinical laboratory professionals. They are based on proven clinical laboratory standards and accepted good laboratory practices. These standards reflect requirements for procedures that are performed in the laboratory environment and are necessary for any laboratory to produce consistently accurate results. COLA standards have been deemed to be equivalent to the federal CLIA regulations. The following sections describe some of COLA's standards in comparison to CLIA regulations. Standards discussed include personnel, proficiency testing, and quality control.



COLA Has Been Granted “Deeming Authority” by CMS

“Deeming authority” is a status granted to COLA by CMS that recognizes that COLA's accreditation standards are equivalent to, or more stringent than, the federal government standards. Laboratories accredited by COLA fulfill CLIA requirements and COLA accredited labs are not routinely inspected by the government. As a result of being granted deeming authority, some COLA criteria mirror federal CLIA requirements.

Laboratories Must Comply with State Requirements in Addition to CLIA Requirements

Some states have specific regulations that govern laboratory operation. Some states have applied for and been granted “exempt” status because the state laboratory regulations have been deemed to be at least as stringent as CLIA. Whether your state is “exempt” or just has specific laboratory regulations, COLA accredited laboratories must comply with all applicable state regulations.

Exempt states: New York, Washington

Currently additional states with laboratory regulations are: California, Connecticut, Florida, Georgia, Hawaii, Louisiana, Maryland, Massachusetts, Montana, Nevada, New Jersey, North Dakota, Pennsylvania, Rhode Island, Tennessee, West

Personnel Standards

COLA's personnel standards for accreditation are identical to federal standards. A qualified individual must fill each required position in the laboratory and meet the responsibilities of the position. The laboratory director and laboratory personnel must meet education and experience requirements to qualify to hold their positions in the laboratory. The laboratory director is responsible for the overall operation of the laboratory. Certain duties of the laboratory director may be delegated to qualified individuals, but the laboratory director remains ultimately responsible.

Refer to **Personnel** in Section III for the chart detailing the specific requirements and qualifications for each laboratory position in a non-waived (moderate or high complexity testing) laboratory.

Keep in mind that several states require laboratory personnel licensure, and may have more strict qualification requirements. Currently, these are: California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, North Dakota, Rhode Island, Tennessee, and West Virginia.

Proficiency Testing

CLIA and COLA require laboratories to participate in proficiency testing (PT) for **regulated** analytes only. COLA also strongly recommends participation in PT for unregulated analytes and waived tests. See new COLA criteria WAV 10, which requires PT for waived testing. At this time, this criterion is considered educational only, and will not constitute a deficiency citation if cited during your survey. Despite the regulatory emphasis given to proficiency testing for regulated and non-waived analytes by CMS, COLA believes that proficiency testing is an integral part of quality laboratory practice that has value for all testing.

Proficiency Testing Failures

Like the federal CLIA requirements, COLA standards require that a laboratory failing a single testing event ("unsatisfactory performance") take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory's records.

Laboratories with repeated PT failures ("unsuccessful performance") must also take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory's records. In addition, laboratories with unsuccessful PT performance must provide COLA with written documentation of the corrective action taken.

Under COLA, laboratories with continuing unsuccessful PT performance will be asked to cease testing the regulated analyte, specialty, or subspecialty exhibiting the problem. To rectify the cease testing, the COLA laboratory must meet COLA's reinstatement requirements, which, like CLIA, includes a mandatory six-month cease testing.

Quality Control

Like the CLIA requirements, COLA laboratories must establish a quality control (QC) program for all tests performed in the laboratory. Tests classified as waived must, at a minimum, follow the quality control recommendations specified by the test manufacturer, but COLA strongly recommends that you develop a QC program for these tests as good laboratory practice and to ensure the accuracy of your waived tests.

Personnel standards, proficiency testing, and quality control are some of the important aspects of COLA Accreditation. More details about the accreditation standards relevant to these and other areas are presented in Section III.

COLA's Reporting Obligations to CMS

COLA is accountable for keeping CMS informed of the status of its accredited laboratories. COLA is required to contact CMS if a laboratory has deficiencies that pose an immediate risk of harm to patients or to the public health, or if we receive substantiated complaints about a laboratory. Even though COLA is required to contact CMS in certain situations, COLA will work directly with the lab to correct problems in the laboratory.

COLA is required to report the following situations and information to CMS:

- Identification of a deficiency at an accredited laboratory that poses a risk of harm to the patients or is a hazard to public health (within 10 days)
- Final actions of the COLA Board of Directors to withdraw, revoke, limit, deny, or suspend a laboratory's accreditation (within 30 days)
- A laboratory that adds a new specialty or subspecialty (within 30 days)
- "Cease testing" actions taken against a laboratory due to repeated proficiency testing failures (within 30 days)
- Scheduled and completed surveys
- A laboratory ineligible for CLIA certification (due to a CLIA judicial action against an owner, operator, or employee of the laboratory) applies to COLA for accreditation

In addition, CMS requires COLA to:

- Provide information about an accredited laboratory's proficiency testing to any person requesting it
- Notify each of its accredited laboratories within 10 days in the event that COLA's deeming authority is withdrawn by CMS

For the most part, COLA-accredited laboratories deal directly with COLA and COLA staff. COLA laboratories must meet COLA standards. However, your laboratory has additional obligations to meet in order to comply with CLIA and state regulations.

You are responsible for:

- Obtaining a Certificate of Accreditation from CMS every two years
- Paying CMS the appropriate fees
- Obtaining a state license, if applicable in your state
- Complying with all state laboratory regulations, including personnel licensure, when applicable
- Complying with COLA standards
- Permitting CMS to conduct an inspection if a complaint is lodged against your laboratory
- Permitting CMS to conduct a random validation inspection
- Notifying CMS and COLA within 30 days of any changes in ownership, name, location, or director of the laboratory
- Notifying COLA within 60 days of any changes to personnel, instruments, or test menu, especially when adding new specialties of testing

When CMS Becomes Involved

So long as a laboratory complies with COLA standards, it will remain accredited under COLA's umbrella. However, if a laboratory willfully disregards COLA standards, it will be denied accreditation. At this point, the Laboratory will be subject to CMS inspection, certification program, and federal sanctions (See Denial of Accreditation in Section III).

COLA's approach to accreditation is educational and service-oriented. COLA cannot levy CMS sanctions such as civil monetary penalties, on-site monitoring, and/or suspension of Medicare payments.

When a laboratory undergoes a validation or complaint inspection by CMS, the situation is different. If CMS identifies a deficiency sufficient to require sanction, then the federal government may sanction the COLA laboratory. Additionally, COLA is required to release to CMS unsuccessful proficiency testing results. CMS may take an adverse action against a laboratory that fails to participate successfully in an approved PT program, refers PT samples to another laboratory, or communicates PT results prior to the PT program end date for submission of results.

COLA's Obligation Regarding Information Transfer to The Joint Commission

The Joint Commission recognizes laboratory accreditation by COLA for laboratories that are affiliated with organizations accredited by The Joint Commission. The goal of this cooperative effort is to eliminate duplicative processes and lower costs to our respective participants.

COLA will conduct routine surveys of laboratories that are affiliated with organizations accredited by The Joint Commission on an unannounced basis. Laboratories that are receiving their first COLA survey or have an annual test volume of 25,000 or less will be given notice of five (5) business days prior to the start of the survey. During the year between on-site surveys, Joint Commission laboratories are expected to perform COLA's Self-Assessment using the Criteria for Quality Laboratory Performance to ensure continuing compliance with COLA and CLIA requirements.

As part of this agreement with The Joint Commission, COLA has agreed to make publicly available a laboratory's accreditation status. This policy is limited to those laboratories accredited by COLA that are affiliated with healthcare systems accredited by the Joint Commission.



IMPORTANT

Know Your Laboratory's Responsibilities to Regulatory Agencies

For CMS certification...fees and inspections...state license...notifications.



State and Federal Agency Contacts: Don't Know Where to Call?

Staff at COLA, (800) 981-9883, can help you with questions you may have about keeping federal and state regulatory agencies informed, and about proper procedures for notification.

For example, COLA staff can provide you with phone numbers of contacts in your state's regulatory agency that have information about state licensing requirements.

Notes



IN THIS SECTION

The Road to Accreditation: Important Facts You Need to Know	18
Step 1: Enrollment and Completion of Forms	20
Step 2: Completing the Self-Assessment.....	21
Step 3: On-site Survey.....	22
Getting Ready: Planning for the Survey Day	
Documents Necessary for the On-site Survey	
Additional Notes to Help You Prepare for the Survey	
Proficiency Testing	
Quality Assessment	
The Survey Day	
Summary Conference Provides Feedback	
Step 4: Post-Survey and Corrective Action.....	27
Processing Survey Data and Reporting Results	
Completing the Plan of Required Improvement (PRI)	
The Laboratory's Responsibilities During the PRI Process	
After the Survey: Action Timeline From Survey to Accreditation	
If Your Laboratory is Found to be in Full Compliance with COLA Criteria	
If Your Laboratory is Found to be Noncompliant With One or More of COLA's Criteria for Lab Performance	
Other Requirements That May Apply Until Noncompliance is Corrected	
Step 5: Accreditation	30
Laboratory Excellence Award for Superior Performance	
Transfer of Accreditation Other Issues Related to the Accreditation Process:	
Appeals, Withdrawal <i>With Notice</i> , Probation, "Risk of Harm," Denial, Complaints	

5 Key Steps in Accreditation

1. Enrollment

You have already been accepted into the COLA Accreditation Program and your immediate task is to become familiar with this Manual and with the information in the laboratory packet that has been provided to your laboratory. Participate in proficiency testing and authorize your PT provider to release results to COLA for ongoing monitoring. Enroll in COLAcentral® at www.colacentral.com, where you will access all your lab's important accreditation documents.

2. Self-Assessment Questions

COLA's Self-Assessment is designed to reveal information that will help determine the current practices of your laboratory in relation to COLA's criteria for laboratory excellence. COLA will review your responses and assess your laboratory's strengths and improvement needs.

3. On-site Survey

A COLA surveyor will visit your facility, interviewing your staff and looking at records to evaluate compliance with COLA criteria. The COLA surveyor will develop a report of findings and share them with you.

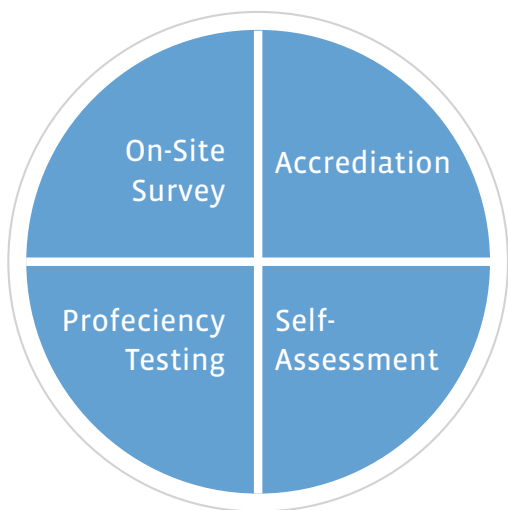
4. Post-survey Feedback and Corrective Action

Your COLA surveyor will provide you with in-depth feedback, verbally and through written documents, regarding their findings about your laboratory. If noncompliant criteria are identified, then COLA will provide your lab a Plan of Required Improvement letter. With COLA's guidance, your laboratory will take charge to develop and implement corrections to address any noncompliant criteria.

5. Accreditation

Accreditation is granted to a lab after it successfully participates in a COLA on-site survey and meets all other COLA standards and criteria as described in this Manual.

COLA Accreditation Flow



Accreditation Overview

COLA accreditation is a multi-step educational process that promotes excellence in clinical laboratory operation as a foundation for meeting the regulatory requirements of COLA and CLIA.

Step by Step: COLA Accreditation Process

Step 1 Enrollment	Step 2 Self-Assessment	Step 3 On-site Survey	Step 4 Post-survey Feedback and Corrective Action	Step 5 Accreditation
<ul style="list-style-type: none"> • Lab pays fees and receives information packet and Manual • Lab reads instructions from COLA and submits all required information • Lab authorizes their PT provider to release results to COLA for ongoing monitoring 	<ul style="list-style-type: none"> • Lab conducts the Self-Assessment and submits the information to COLA • Lab makes improvements needed to comply with all COLA criteria 	<ul style="list-style-type: none"> • Scheduling for on-site survey • Lab compiles and organizes documentation required for review • COLA surveyor performs onsite survey • COLA surveyor shares survey findings and provides educational guidance to the lab staff 	<ul style="list-style-type: none"> • COLA carefully analyzes site data and prepares report • COLA issues formal post-survey report • If noncompliant criteria are identified, the lab plans and acts to correct them, providing COLA with documentation of corrective action 	<ul style="list-style-type: none"> • Lab receives COLA Accreditation Certificate (updated every two years)

The Road to Accreditation: Important Facts You Need to Know

Accreditation is Education-Oriented

Education is an integral part of the COLA accreditation process and the laboratory staff must embrace a mindset of learning and continuous improvement to succeed in this program. The COLA Self-Assessment and COLA Criteria for Quality Laboratory Performance are the foundation for this process. COLA LabUniversity® courses supplement learning.

The **COLA Criteria for Quality Laboratory Performance** are the guiding principles for achieving a quality-conscious laboratory which takes appropriate action to ensure accurate test results for all tests performed in the laboratory. Studying these criteria can help improve the operation of any laboratory.

Performing the **Self-Assessment** helps you identify areas of noncompliance and improve your laboratory system as you prepare for the on-site survey. Improvements you make will increase the level of satisfaction of your patients and laboratory staff.

To complement these educational tools, the COLA **On-site Survey** is also designed to be educational rather than punitive. COLA staff are trained to help participants understand where the laboratory operation needs improvement and how to make improvements.

COLA offers a number of educational resources to expand your skills and knowledge, including the on-line Laboratory Director Education Program, COLA's "Quality Assessment Plan, A Simplified Approach," and COLA's OSHA Self-Assessment.

Accreditation is a Multi-step Process

COLA accreditation is a multi-step process, giving laboratories the time to identify their strengths and weaknesses and develop an action plan for improvement with the guidance and support of COLA staff.

Achieving Accreditation Requires Strong Staff Commitment

The laboratory director must take personal initiative and responsibility to learn the requirements and develop the skills necessary to achieve compliance. Relaying this commitment to staff, providing leadership, and involving them in the process is important to achieve accreditation.

You Must Meet COLA Standards for laboratory Performance

The COLA accreditation program features a set of standards, called *Criteria for Quality Laboratory Performance*, which your laboratory must meet to fulfill compliance requirements and earn accreditation.

The COLA standards, which are based on years of clinical experience, will help ensure that your laboratory is developing the quality habits and practices of a high performing laboratory at an early stage of your participation in the program.

These standards reflect procedures that are generally accepted in the clinical laboratory and are necessary for any laboratory to produce consistently accurate results.



QUICK TIP

The COLA Criteria for Quality Laboratory Performance and the Self-Assessment questions are one and the same.



Quench Your Thirst for Knowledge

COLA offers educational resources and on-line courses on a wide variety of laboratory operation topics. Check out www.labuniversity.org for information



IMPORTANT: Know COLA's Standards for Performance

The COLA standards are shown in detail in Section III of this Manual – Criteria for Quality Laboratory Performance. The following are evaluated by COLA to determine if a laboratory meets COLA standards:

- Organization
- Facility
- Lab Director Responsibilities
- Personnel
- Proficiency Testing
- Laboratory Information Systems
- Pre-analytic Activities
- Procedure Manual
- Maintenance
- Verification of Performance Specifications
- Calibration
- Quality Control
- Waived Testing
- Specialty Specific Criteria
- Post-analytic Activities
- Quality Assessment
- Immunohematology / Transfusion Services



Your Responsibilities in the Accreditation Process

Your organization, with the assistance of COLA, will be responsible for taking leadership for the following actions during the laboratory accreditation process:

Your laboratory will...

- Carefully review this Accreditation manual and complete the forms and promptly respond to other information requests from COLA
- Enroll in COLAcentral® and maintain at least two active users. .
Notify COLA if you are unable to access COLAcentral®.
- Meet other regulatory notification and procedural requirements as stipulated by federal and state agencies
- Develop a comprehensive action plan for performing the Self-Assessment, involving staff members
- Assess and ensure compliance with qualifications and responsibilities of the laboratory director and each CLIA-required laboratory position
- Educate and train personnel to ensure skill and competency requirements are met for quality laboratory performance
- Take timely corrective action for identified noncompliances.

Accreditation: Checklist for Action

Accreditation is granted to a laboratory once it meets all COLA standards and criteria, and completes the following actions (check off each item as you complete it):

- Pays all fees
- Meets personnel requirements
- Meets applicable state laboratory requirements
- Enrolls in an approved proficiency testing program
- Continues to be successful in proficiency testing
- Submits all laboratory information via COLAcentral® and returns all required signature forms
- Maintain active COLAcentral® accounts for two users
- Notifies COLA of changes in its personnel, test menu, or instrumentation



IMPORTANT: Meet Deadlines & Take Required Action

Some information requests and corrective action responsibilities require timely action by laboratory staff. Make sure you adhere to the requirements within the various stages leading toward accreditation.

Also, look for material throughout this Manual that outlines important information about responsibilities the laboratory must fulfill and actions it must take during accreditation.

Step 1: Enrollment and Completion of Forms

Upon receipt of your application form and payment of your enrollment fees, COLA welcomes your laboratory to the Accreditation program and provides this Manual and other information that starts you on the path to accreditation.

Your enrollment in the COLA program is valid for a two-year period from the date of enrollment, regardless of when the on-site survey is performed.

Carefully Review Your Laboratory Information Packet

The welcome packet your laboratory receives from COLA includes a notification of enrollment letter, a Laboratory Information Packet, and the COLA Accreditation Manual CD.

The page included in the packet titled “Welcome to COLA: Please read this important information immediately” should be read thoroughly. This page includes a handy checklist you can use as a guide to help make sure you are providing all information and notifications required as you begin the accreditation process.

The packet includes three forms that you must complete, and submit to COLA with the Lab Director’s signature. These forms are:

- Form VI – Lab Director Signature Form – this is a form that delineates the agreement between COLA and the laboratory.
- Form IX – Annual Test Volume – this is the form used to report your lab’s annual test volume.
- Form XI – Proficiency Test Data Release Form – this form authorizes your PT provider to release your PT results to COLA. This form **MUST** be submitted to your PT provider, and a copy then submitted to COLA.

The other forms included in your packet are for other important information that you need to submit to COLA. The easiest way to submit the information is by using our customer portal website, COLAcentral®. Go to www.colacentral.com to register. If you are unable to enter the data online, then you have the option of filling out all forms and sending to COLA.

The packet also contains the forms to perform your Self-Assessment, which is described in the next step.



IMPORTANT ACTIONS to Take Right Away

- Your laboratory must apply for or change your current CLIA certificate to a Certificate of Accreditation and pay CMS the required fees.
- Your laboratory cannot perform patient testing without a valid CLIA certificate.
- Notify your state survey agency within 30 days of enrollment in the COLA accreditation program.
- Complete and submit the forms (answer all questions as instructed) in the laboratory information packet within 21 days.
- Submit the PT data release form to your PT provider to release your PT scores and send a copy to COLA. **COLA Can Provide Help, Answer Questions** Contact COLA if you need information about how to complete any of the action steps described above. Call COLA at (800) 981-9883, or send an e-mail to COLA at info@cola.org.

Step 2: Completing the Self-Assessment

Completion of the laboratory **Self-Assessment** is one of the most helpful steps in the accreditation process.

COLA has developed the Self-Assessment as a means for you to evaluate your laboratory before the on-site survey. You can then begin to make improvements needed to become a high-performing quality laboratory.

As you complete the Self-Assessment, indicate whether or not your laboratory is in compliance for each applicable criterion. Be honest in your answers, indicating what your laboratory is currently and actually doing, not what you have become aware that you should be doing.

COLA has found that laboratories that complete the Self-Assessment and put a lot of effort into the process have done better, as a whole, on their on-site surveys. These laboratories generally have greater awareness of the requirements and have had the opportunity to come into compliance before the on-site survey takes place.

The Self-Assessment questions are the COLA Criteria for Quality Laboratory Performance, and these are the same questions used by the COLA surveyors to evaluate your laboratory during your on-site survey.

At the end of the Self-Assessment process, you should be able to predict how your lab will perform during the COLA on-site survey. This educational activity is designed to guide the laboratory director toward the goal of improved laboratory performance.

To complete the Self-Assessment, first submit your test menu to COLA. This will allow COLA to customize the Self-Assessment to include criteria that are applicable to the testing specialties performed in your laboratory. After you have submitted your test menu and all other required information to COLA, log on to COLAcentral®, then chose the Management/Compliance tab, and click on “Self-Assessment” and follow the instructions for completion. If you are not able to submit the Self-Assessment using COLAcentral®, you may complete and submit the paper forms that are included in your welcome packet.

When you submit your completed Self-Assessment to COLA, your responses will be reviewed for noncompliant criteria. If noncompliant criteria are found, COLA will provide helpful information back to you to address these problems, so improvements can be made before the on-site survey.

COLA suggests you make appropriate changes in laboratory operations, processes, and procedures to comply with COLA’s accreditation criteria prior to the on-site survey.

We recommend that the lab repeat the Self-Assessment (including submitting the lab’s responses to COLA for feedback) in each two-year cycle to assure continual compliance, quality performance, and readiness for subsequent on-site surveys.

Complete the Self-Assessment when adding tests in a new specialty or subspecialty in addition to each two-year cycle.



To Locate Your Self-Assessment...

You’ll find the Self-Assessment (COLA Criteria for Quality Laboratory Performance) in Section III. You can complete the Self-Assessment online using COLAcentral®. Go to www.colacentral.com, chose the Management/Compliance Tab, then click on “Self-Assessment” and follow the instructions to complete the Self-Assessment.

It is best to complete the online Self-Assessment a few weeks AFTER you have submitted all of your information to COLA, so that your Self-Assessment will be customized to include the criteria that apply to the testing specialties performed in your lab.

Alternatively, you may fill out and submit the paper Self-Assessment answer sheets included in your packet.



Refer to the Accreditation Criteria in Section III

Use the criteria described in Section III of this Manual to complete the Self-Assessment and as a guide to operate your laboratory. Your goal in completing the Self-Assessment is to honestly evaluate how well your laboratory complies with those criteria so you can prepare for your on-site survey. Think of it as “studying for the test.”

The Self-Assessment can be performed electronically using COLAcentral®.



Laboratory Director and Staff Participation

The laboratory director's role and participation is very important as **the lab director is ultimately responsible for all phases of the laboratory's operation**. COLA encourages the lab director to take an active role in the survey. **However, his/her presence during the survey is not mandatory, and the director's absence is not a valid reason for canceling or rescheduling a survey.**

Arrangements can be made for the surveyor to speak to the director by phone to review survey findings.

It is essential that the individual(s) most familiar with your laboratory's policies and procedures be present to guide the surveyor through the laboratory and be available to answer questions. Any consultants you work with are encouraged to be present to observe the survey.

Step 3: On-site Survey The On-site Survey Process

- COLA reviews your hours of operation to schedule a time for the survey visit
- You receive notification about the on-site survey
- You gather documentation requested for the on-site review
- You make sure you meet all COLA criteria
- COLA surveyor performs the on-site survey, assessing workflow, laboratory support structure, processes, and compliance with COLA criteria
- Your surveyor provides findings at a summary conference

Getting Ready: Planning for the Survey Day

COLA surveyors normally visit each laboratory once every 20-24 months to determine if it meets COLA's standards for accreditation. In general, the survey will be scheduled prior to the two-year anniversary of the last survey.

Your laboratory will have an opportunity to schedule a convenient time for the survey by submitting its hours of operation and noting the dates it would be impossible to accommodate a survey ("blackout dates"). Each lab is allowed up to 10 blackout dates each survey cycle. Blackout dates must be submitted **no later than 20 months** after the date of the last survey. Your flexibility and cooperation are appreciated in scheduling the visit.

Written notification of an approaching COLA survey, along with information on how to prepare for the survey, will be provided to your laboratory in advance of the survey date, unless unannounced survey is required. Allowable notice is determined by regulatory agreements, such as with The Joint Commission.

Once the Survey Date is Confirmed

Your laboratory will receive confirmation of the date of the survey and the name of the COLA surveyor, unless unannounced surveys are required by a regulatory agreement. Please keep in mind that requesting COLA to reschedule your survey will incur a rescheduling fee.

Laboratories are required to notify COLA of any changes to test menu, instrumentation, personnel, and ownership within 60 days of the change. Use COLAcentral® to update your lab's information. If you have changes the surveyor was not aware of, then this will extend the time the surveyor is there and could impact the schedule of other laboratories.

Additional Notes to Help You Prepare for the Survey

As noted above, during your on-site survey your documentation, Proficiency Testing (PT), and Quality Assurance (QA) activities will be reviewed. A closer look at documentation, record keeping, PT, and QA requirements is provided below.

Document all laboratory activities, including:

- Laboratory policies, processes, and procedures
- Personnel training and competency assessments
- Test requests
- Instrument maintenance and function checks
- Temperature checks
- Test system performance specifications
- Calibrations and calibration verifications
- Patient test results and quality control results
- Proficiency Testing
- Quality Assessment Plan and QA reviews for all areas in the laboratory path of workflow.

Most records must be maintained for a minimum of two years (Immunochemistry records are kept longer). Store records in a way that ensures their preservation and easy retrieval for review by the COLA surveyor.

The detailed requirements for documentation and record retention can be found in the COLA Criteria for Quality Laboratory Performance (Section III).

Proficiency Testing

Proficiency Testing (PT) is an important tool to assess accuracy and meet laboratory regulations. COLA monitors the lab's performance in PT, and uses the same requirements and grading criteria as the federal government. Enroll and participate in PT for all regulated analytes on your test menu. Records of corrective actions for unsatisfactory performance in PT must be available.

COLA strongly recommends that labs perform PT on unregulated analytes as an added measure of quality. If the lab is not enrolled in PT for unregulated analytes on its test menu, then some form of external comparison, such as split specimen analysis, must be performed twice yearly. The detailed requirements for PT can be found in the COLA Criteria for Quality Laboratory Performance.

COLA also has a new educational requirement for PT on waived tests. See criteria WAV 10.

Approved Proficiency Testing Providers

COLA is not a Proficiency Testing (PT) provider, but does monitor your facility's PT performance and offers guidance to help you achieve successful results.

COLA will recognize any CMS-approved PT program, and we have an agreement to exchange data with all these providers. See appendix of this Manual for a list of approved PT providers. Further details about approved PT providers can also be found on the CMS website.

The surveyor will need the documentation described below, including patient charts when requested, for a two-year period prior to the survey, or from the date of the last COLA survey or other CLIA inspection.

These records should be collected just prior to the survey and placed in a room with an electrical outlet. The list below is not all-inclusive, but represents the basic items required. Depending on individual circumstances, the surveyor may request additional records.

Please have the following available: Copy of current CLIA certificate for surveyor to review and copy if required.

Copy of current Annual Test Volume calculations for surveyor to verify along with a copy of the completed Annual Test Volume Form that was previously sent to COLA.

Personnel files for each laboratory employee (including physicians) performing non-waived testing. Files must include:

- Proof of education according to CLIA 88 requirements. The following documents are acceptable: High school diploma, GED, Transcripts (must have date graduated), college degrees (AS, BS, MS, and PhD), and MD/DO licenses.
 - MT and MLTs **must** have either copies or transcripts of the advanced degrees (AS, BS, MS). ASCP or other professional society cards or certificates cannot be accepted as the only proof of qualification.
 - Medical Assistants, LPNs, and RNs **must** have either high school diplomas or advanced degrees available. Licenses cannot be accepted as the only proof of qualification.
 - Those employees with only foreign educational documents **must** have them evaluated for equivalency to a US high school diploma, or college degree. (Please contact COLA for a list of evaluation organizations).
 - In those states that license laboratory personnel, a copy of a current state license can be accepted. It is advisable to have copies of the corresponding educational degree as well.
- Written performance evaluations and/or technical skill competencies. New employees must be evaluated at six months and also one year after their hire; other employees must be evaluated yearly.
- Records listing laboratory-related continuing education and annual OSHA/Bloodborne Pathogens training.
- Training documents for all new employees or some proof of their previous experience, such as resumes and prior instrument training.
- Job descriptions for all employees.

Policy and Procedure Manual(s) including all instrument Operator's Manuals

- Current package inserts for all kit tests and reagents (including all waived methods)
- Current package inserts for all controls and calibration materials used during the survey period
- Proficiency Testing (PT) records including instrument tapes, test report forms, attestation statements, graded results, and corrective actions taken for all unsatisfactory scores, and evidence of self-evaluation of any ungraded results
- Instrument / equipment / pipette calibration, maintenance, and function check records for current and discontinued instruments used during the survey period

- ❑ Temperature and humidity records
- ❑ All quality control (QC) records, graphical representations, charts, and any other documentary logs involved
- ❑ Test requisitions and report forms used for all laboratory testing; The surveyor may ask to review several patient charts.
- ❑ Quality Assessment (QA) Plan and documentation of implementation, with QA reviews. For assistance consult COLA LabGuide 70 or contact your COLA Technical Advisor
- ❑ Incident Management Plan and any reports (see COLA LabGuide 71)



Proficiency Testing Requirement

Your laboratory must enroll in a CMS-approved Proficiency Testing (PT) program as a requirement of COLA accreditation. You must remain enrolled with an approved PT program for one calendar year before changing enrollment to another approved PT program.

Quality Assessment

Quality Assessment (QA) is distinct from quality control. Quality control monitors the analytic process of testing a specimen. A quality assessment program helps standardize testing in the laboratory, identifies sources of error in patient testing, and includes regular monitoring and evaluation of all aspects of the laboratory's activity, from specimen collection to the delivery of the report to the physician.

A QA program evaluates each "process" in the laboratory: quality control, proficiency testing, personnel training, test tracking, laboratory communication, and all error correction procedures. It provides laboratory staff with a road map to identify and investigate problems in these laboratory processes, to develop appropriate corrective actions, and to perform follow-up review to be sure problems are corrected. Continuous improvement and error prevention is the goal.

The Survey Day

Introductions and Laboratory Tour

After introductions, the surveyor takes a tour of your laboratory. During this tour, the laboratory's instrumentation is checked against the data you previously submitted to COLA, and the laboratory's workflow is observed. After the tour, the surveyor requests a place where the documentation can be reviewed.

The surveyor evaluates your laboratory's compliance with the COLA criteria and will take time to answer questions and educate staff about good laboratory practices.

An In-Depth Look at the Documentation

The surveyor uses the documentation provided to verify policies, procedures, record-keeping, quality control and quality assessment reviews, and corrective actions. The test menu and complexity of testing performed at the lab is confirmed. These records are also instrumental in evaluating personnel for their ability and qualifications to perform the level of testing evident at the lab. Patient test results are compared to worksheets and/or instrument printouts. After the paperwork review, the laboratory is checked for other criteria that reveal laboratory conditions and compliance.

Laboratory staff may be questioned to determine their understanding of quality laboratory processes and required procedures. If the surveyor has any questions about a particular laboratory worker's ability to perform a given test, the surveyor may ask the laboratory worker to perform the test and observe whether it is done properly. The surveyor can refer the lab to educational materials available from COLA.

Evaluation of Workflow

Drawing upon information from interviews, observations, and documentation, COLA's surveyors will evaluate the laboratory's path of workflow and its ability to produce accurate and reliable results in a timely manner.

Summary Conference Provides Feedback

The final phase of the on-site survey is the summary conference, which is held between the COLA surveyor and the laboratory director, the laboratory staff, lab consultants, and any other staff the laboratory director invites. The purpose of the summary conference is to provide a general overview of the survey findings and to discuss the next steps to complete the accreditation process.

During the summary conference, the surveyor emphasizes the educational resources available to help the laboratory staff resolve any problems or areas requiring attention. This is also an opportunity for the surveyor to congratulate the laboratory director and staff when the laboratory is found to be in compliance with COLA criteria.

The surveyor gives the laboratory director or representative a preliminary report of any noncompliant criteria, reviews the remaining steps in the accreditation process, and explains that official written notification of any noncompliant criteria will follow. The laboratory director is asked to complete a survey evaluation online.

The overwhelming majority of laboratories report that the on-site survey is a helpful, educational process. Most laboratories are already quality-focused, and therefore look forward to suggestions that will help them comply with regulations and run an accurate and efficient laboratory.

Step 4: Post-Survey and Corrective Action

Processing Survey Data and Reporting Results

The data gathered by the surveyor is transferred electronically to COLA. A report is promptly initiated detailing whether the laboratory meets COLA accreditation requirements.

The summary conference described earlier provides the laboratory with immediate, informal feedback about what was learned from the on-site survey. However, complete results of the survey will be provided to you in the **Plan of Required Improvement**.



At a Glance: Corrective Action Process

If the COLA survey identifies noncompliant criteria that must be corrected prior to accreditation, here's the sequence of events:

- Your laboratory will receive a Plan of Required Improvement (PRI) that provides guidance for follow-up documentation and other actions the laboratory must take to address deficiencies
- The PRI package includes a report that provides details about areas of noncompliance
- You are expected to take charge to develop and implement a plan to correct each noncompliance
- The laboratory director must sign and submit an agreement within 14 days of receipt of the PRI indicating commitment to correct all noncompliant criteria in a timely manner
- For some noncompliant criteria, you are expected to provide COLA with timely documentation that demonstrates proof of corrective action
- In some cases the lab may be required to complete educational courses based on the areas of noncompliance
- Under certain circumstances, you may be requested to cease testing or take other actions as requested by COLA
- Once all noncompliant criteria have been addressed, and any requested documentation meets with COLA approval, you will be granted accreditation.

Taking Corrective Action

Completing the Plan of Required Improvement (PRI)

If the survey results indicate that your laboratory is not in compliance with all of the COLA criteria, you will receive a Plan of Required Improvement (PRI). The PRI contains detailed instructions concerning necessary improvements, documentation required from the laboratory to prove completion of the plan, and whether the laboratory is subject to probation or resurvey.

The Laboratory Responsibilities During the PRI Process

Develop a corrective action plan for each noncompliance.

In each instance where COLA identifies a noncompliance that requires corrective action, the laboratory is expected to take charge and correct the noncompliance following the schedule and guidelines provided by COLA.

Provide COLA with Documentation Showing Proof of Corrective Action. The laboratory may also be required to provide COLA with timely documentation that demonstrates proof of corrective action – closely following the actions indicated in the Plan of Required Improvement.

Provide Any Needed Training. Your corrective action plan should factor in any employee training needs to support your required improvements.

Additional Information. If the laboratory director agrees to correct noncompliances in a timely manner, the laboratory is approved for accreditation upon providing the signed agreement and any documentation requested.

If the noncompliances are of a more serious nature, the laboratory is required to correct them in a more expedient manner and to send COLA additional information documenting actions it has taken to correct the problems. The laboratory may be placed on probation for a specified time period during which additional mentoring by COLA staff may occur. If major noncompliances are found, COLA reserves the right to impose other requirements, such as a resurvey or completion of relevant educational courses at the laboratory's expense.

While COLA makes every attempt to contact laboratories, those that fail to respond to COLA correspondence may be denied accreditation.



Deadline for PRI Response

The laboratory director has 14 days to agree to the PRI or to appeal to COLA. The PRI asks the laboratory director to sign the agreement form and submit it to COLA, stipulating intent to correct all noncompliant criteria. The agreement and any required documents may be uploaded by using COLAcentral®.



Report Shows Details About Areas of Noncompliance

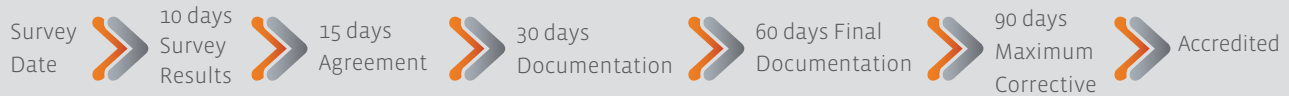
When a laboratory receives a Plan of Required Improvement, it will include the following components:

- Due dates for submission of the agreement and any documentation required
- A summary showing the total citations, number of repeat citations, and number of citations requiring documentation
- A Peer Review Comparison shows your laboratory's performance compared to that of other COLA labs having the same annual test volume.
- A listing of the personnel and test & test systems at the time of the on-site survey
- A Grouped Citations and Actions Required table. This table lists each citation, and identifies any repeat citation with an asterisk. It includes the reason the surveyor cited the criterion, a list of actions to be taken to address each citation, and if required, a description of the documentation that needs to be submitted to COLA as evidence of correction.

COLA will not release this laboratory-specific information to others without permission from the laboratory director.



After the Survey: Action Timeline From Survey to Accreditation



If Your Laboratory is Found to be in Full Compliance With COLA Criteria...

10 days after the on-site survey, your laboratory will receive notification of your results and a COLA Accreditation Certificate

If Your Laboratory is Found to be Noncompliant With One or More of COLA's Criteria for Laboratory Performance...

- *10 days after the on-site survey, your laboratory will receive a report of your results in a Plan of Required Improvement (PRI)*
- *When you receive your PRI, here are the deadlines you must keep in mind...*
 - *Your signed agreement form to correct all noncompliances must be received by COLA no later than the date indicated in your PRI (14 days)*
 - *Your survey documentation, as requested by COLA must be received by COLA no later than the date indicated in your PRI (30 days)*
 - *Under special consideration, laboratories that require additional documentation may be permitted to submit final documentation later than the date indicated in your PRI (60 days)*

Other Requirements That May Apply Until Noncompliance is Corrected

In addition to actions described above, COLA may request one or more of the following additional steps or actions be taken in response to noncompliances...

- Cease Testing...
- If noncompliance creates "risk of harm" conditions, the laboratory must correct the noncompliance prior to resumption of testing
- In the event of repeated unsuccessful Proficiency Testing, the laboratory must either delete the test or follow COLA's reinstatement requirements, which includes cease testing for six months. PT is tracked separately from the on-site survey and cease testing notices will be sent at any time, as warranted
- Technical Consultant Oversight – A technical consultant may be required for a time period or indefinitely, depending upon the severity of noncompliances
- Training – May be required for various reasons (e.g. training in instruments, quality control, general lab operations, PT). If cease testing is also an issue, training may be required prior to resuming testing
- Future Documentation – In some instances, ongoing documentation is required (e.g. daily quality control) for specified time periods
- Resurvey – In severe cases, a resurvey at the laboratory's expense may be necessary. These are unannounced and are scheduled within a reasonable amount of time to allow the laboratory to complete corrective action
- Educational courses – targeted to specific areas of noncompliance may be required

Step 5: Accreditation

Congratulations! After successfully correcting any noncompliant criteria noted in your on-site survey report, your laboratory will be accredited until the earliest date of:

- Your next on-site survey, or
- The expiration of your COLA enrollment, or
- Your withdrawal from COLA (or denial of accreditation).

Laboratory Excellence Award for Superior Performance

COLA is sensitive to the extra effort that certain laboratories have taken to demonstrate superior performance. Therefore, COLA created the **Laboratory Excellence Award** for COLA laboratories that show exemplary performance.

COLA laboratories are eligible if they meet the following criteria:

- Completion of an on-site survey
- Full compliance with COLA Essential and Required criteria
- Documentation of successful performance in Proficiency Testing for the preceding three events
- No substantiated complaints against the laboratory.

Each laboratory earning this award receives a congratulatory letter and a special COLA Laboratory Excellence plaque.

Transfer of Accreditation

COLA accreditation may be transferred with the purchase of a COLA-accredited laboratory when:

- The original owner provides COLA written permission to transfer the accreditation
- COLA is notified of the transfer of ownership of the laboratory within 10 days of the transaction
- COLA is notified of all changes in personnel, location, equipment, test menu, PT provider, and other information required by COLA within 30 days of the transaction
- The laboratory continues to meet the eligibility criteria to qualify for COLA accreditation
- The laboratory continues to meet COLA accreditation requirements
- The laboratory's new owner agrees, in writing, that the laboratory may be resurveyed at the owner's expense prior to the end of the term of accreditation if COLA has reason to believe that:
 - The laboratory may no longer be in compliance with COLA accreditation requirements
 - The laboratory is not eligible for COLA accreditation
 - The laboratory has substantially changed its test menu to include specialties or subspecialties not performed in the original laboratory.

Other Issues Related to the Accreditation Process

On rare occasions, a laboratory may be visited more than once in two years. COLA may conduct an unannounced survey of a laboratory if a formal complaint is lodged against the laboratory.

A very small percentage of COLA accredited laboratories will also be visited by federal or state inspectors for a "validation inspection" to verify that the COLA survey satisfies their requirements. Validation inspections do not imply that the laboratory is under any additional surveillance. Laboratories are required to permit these surveys under CLIA regulations.

Appeals to Plan of Required Improvement

A laboratory director may appeal a PRI if he or she feels that the laboratory already complies with the criteria cited as noncompliant at the time of survey. The laboratory director should provide invoices, copies of laboratory records, and other documentation supporting the appeal. COLA reviews this information, along with other pertinent material provided by the surveyor.

If COLA agrees with the laboratory director, then the PRI, or the specific criteria cited, will be reversed. If COLA still believes the laboratory is not in compliance, then the laboratory is notified that it must still fulfill the PRI as issued.

Voluntary Withdrawal With Notice

A laboratory will be withdrawn from COLA Accreditation with notice when:

- It is subject to denial of accreditation, AND
- It fails to correct the noncompliance causing the denial action, AND
- It EITHER fails to pay renewal fees and lets accreditation lapse, OR notifies COLA that it wishes to withdraw from the program

In these cases, CMS will be notified that the laboratory has been withdrawn with notice and will be provided the issues that lead to the pending denial action.

Probation

A laboratory may be placed in probationary status if any of the following conditions apply:

- The laboratory is in violation of COLA accreditation policy, but does not warrant immediate denial of accreditation
- COLA wishes to monitor the progress of a laboratory in remedying a violation of one of the conditions set forth in the COLA accreditation policy
- The laboratory is referred to the Staff Technical Accreditation Team (STAT) due to conditions discovered during the on-site survey (such as failure to maintain corrective actions) that warrant consideration of denial, cease testing, or resurvey

For each laboratory placed on probation, a defined period of probation will be set by COLA. A laboratory will remain on probation until COLA determines to deny accreditation; or determines that the condition which led to placement on probation has been adequately addressed; or the probationary time has expired, whichever occurs first. Laboratories that fail to remedy violations according to COLA accreditation policy within the defined period of probation will be denied accreditation.

Laboratories That Present a “Risk of Harm”

The most serious situation that faces COLA surveyors is the rare instance in which laboratories perform tests in such a manner as to cause an immediate risk to the health or safety of the patients or laboratory staff.

Situations that may present a “risk of harm” include things such as reporting results on tests not performed (“sink testing”), the presence of unlabeled specimens, inadequate identification procedures in transfusion services, or personnel observed performing phlebotomy with previously used blood collection supplies.

If surveyors encounter these or similar situations, they are instructed to complete the survey and gather as much documentation as possible concerning the conditions. During the summary conference the surveyor informs the laboratory director of the condition which is potentially harmful to patients and asks the director to cease patient testing for the test under question until the problem is corrected.

If the problem is systemic, that is, it pervades the entire laboratory, the laboratory must cease testing altogether until the problem is corrected.

The surveyor then sends the report and associated documentation to COLA for immediate review by the Staff Technical Accreditation Team (STAT). The STAT team will convene within two days and determine if a “risk of harm” exists.

Laboratories will be notified immediately and in writing of what actions to take regarding the risk of harm. Laboratories that fail to respond or fail to promptly correct risk of harm conditions will be subject to denial of accreditation. The laboratory will not be allowed to resume testing until all noncompliant criteria leading to the risk of harm have been addressed to COLA's satisfaction.

Reasons for Denial of Accreditation

As long as a laboratory complies with COLA standards, it will remain accredited and under COLA's umbrella. Should a laboratory fail to comply with COLA standards and be denied accreditation, it will come under the CMS inspection and certification program and be subject to federal standards.

A Laboratory Will be Denied COLA accreditation for the following reasons:

- Failure to promptly correct laboratory activities that pose an immediate risk of harm to patients or employees. This may lead to summary denial which can be appealed by the laboratory
- Failure to enroll in a COLA-approved Proficiency Testing program, or refusal to authorize COLA to receive PT performance reports from its PT provider
- Submitting a Proficiency Testing sample to another laboratory

A Laboratory May be Denied COLA accreditation for the following reasons:

- Failure to comply with reasonable requests of COLA
- Failure to permit a COLA on-site survey, or obstructing the survey process in such a way that the laboratory cannot be adequately evaluated to the satisfaction of COLA
- Failure to adhere to COLA-imposed required improvements
- Misrepresenting information presented to COLA as part of the accreditation process. Such misrepresentation may be oral or in writing, and may be obtained by COLA as part of direct observation. Misrepresentation includes fabrication, in whole or in part, of information or documentation, alteration of records, or misleading COLA into believing the accredited facility is in compliance with COLA accreditation requirements when it is not
- Continuing to test an analyte, specialty, or subspecialty after being directed by COLA to cease testing because of failure to meet proficiency test performance criteria for that analyte, specialty, or subspecialty
- Communicating with any other laboratory pertaining to the results of proficiency tests prior to the PT program end-date for receipt of results

Due Process and Denial of Accreditation

Whenever a laboratory's accreditation status may be denied or limited in some way, the laboratory director always has the right to appeal the decision to the COLA Board of Directors. + COLA staff carefully follows Board policy, uses certified mail or other traceable means to be sure that the director is aware of the denial procedure, and keeps the laboratory informed about its due process rights.

If a laboratory fails to promptly correct laboratory activities that pose an immediate threat of harm to patients or employees, the Chair of the COLA Accreditation Committee will immediately withdraw accreditation. The laboratory may appeal the decision as outlined below.

For other denial actions, if COLA determines that the laboratory meets the criteria for denial of accreditation, a notice of denial is sent to the laboratory director by certified mail or other traceable means. If the laboratory provides a response that answers the concerns, then COLA will stop the denial process. If the laboratory response is inadequate, then COLA will recommend the laboratory to the Chair of the COLA Accreditation Committee for denial of accreditation.

At its next meeting, the Accreditation Committee will consider the facts and make a decision whether to continue the accreditation process or to take other action. If the decision is to continue the accreditation process, then the laboratory will be returned to COLA's normal accreditation procedures.

Any laboratory that has been denied accreditation by the Accreditation Committee will be promptly notified by certified mail or other traceable means.

The notification will include a brief statement of the reason for the Accreditation Committee's decision. It will also explain that the decision is not final and that the laboratory may request an appeal of the decision by following the procedures set forth in the COLA Process and Appeal of Denial Policy that is included with the notice.

If the laboratory fails to file a timely appeal, and is using COLA accreditation for governmental laboratory certification or for an organization for which COLA has a recognition agreement, then a notice of denial of accreditation will be sent to the designated federal and/or state agencies, and other applicable accrediting organizations.

Appeal of Denial to the COLA Board of Directors

Within 14 days after receiving notification of an adverse decision by the Accreditation Committee, the director of the laboratory may file an appeal in writing to the COLA Board of Directors Appeals Committee. Included in the request should be a statement of why the director believes the decision was incorrect, as well as other supporting documents that the director feels demonstrates the laboratory's compliance with COLA standards.

The appeal will be considered by an Appeals Committee consisting of Board members appointed by the Chair of the Board of Directors. Members of the Appeals Committee cannot be members of the Accreditation Committee, and do not maintain practices that could be construed as being in competition with the laboratory under review.

Upon receipt of the appeal, COLA will notify the director of the laboratory by certified mail or other traceable means that COLA has received the request for appeal and that the appeal hearing will be held at the next meeting of the Appeals Committee. The Appeals Committee will be scheduled to meet via teleconference after receipt of a request for appeal. At least 30 days before the meeting of the Appeals Committee on this subject, the director of the laboratory will be notified by certified mail or other traceable means of the date, time, and location of the meeting, and will be provided with copies of any written materials that were used in making the decision of the Accreditation Committee.

The director of the laboratory has the right to participate via tele-conference before the Appeals Committee and be represented by counsel, and may make an oral or written presentation to the Committee. The director must notify COLA in writing within 14 days of the meeting whether he/she will participate and whether legal counsel will participate. COLA will not be responsible for any expense incurred by the laboratory director for attending the meeting.

If the decision on appeal is to reverse the denial of accreditation, then the laboratory will be returned to the normal accreditation sequence.

If the decision on appeal is to uphold denial of accreditation, then a notification will be sent to the director of the laboratory within two weeks by certified mail or other traceable means. This letter will include the reasons for the decision, and advise that this constitutes a final decision by COLA.

If the laboratory is denied COLA accreditation, then a notice of denial of accreditation will be sent to the designated federal and/or state agencies, and applicable accrediting organizations.

Reapplication After Denial

A laboratory that has been denied accreditation may reapply and receive COLA accreditation by meeting the following requirements:

1. A laboratory that has been denied accreditation for submitting a PT sample to another laboratory shall be ineligible for COLA accreditation for one year.
2. A laboratory that has been denied accreditation for any other reason may reapply and receive accreditation but first must be presented to the COLA Enrollment Risk Assessment Committee. The Committee will review the case and render a decision regarding the lab's reapplication. In order for the lab's reapplication to be accepted, the Committee will require that the lab meet the following requirements:
 - Document to the satisfaction of COLA that necessary and appropriated corrections to the deficiencies that resulted in denial of accreditation have been made
 - Meet COLA requirements for accreditation
 - Successfully participate in an on-site survey by a COLA surveyor at the laboratory's expense

Complaints Made Against COLA Accredited Laboratories

COLA evaluates every complaint made about an accredited laboratory. COLA may receive complaints directly from patients, employees of a laboratory, a state agency, or CMS Regional Office.

Notice Requirements

All laboratories are required to post a notice provided by COLA instructing employees and staff how to contact COLA to communicate concerns regarding safety or quality of patient testing performed in the laboratory. The notice must be placed in a conspicuous location visible to all laboratory personnel.



14 Days to Appeal

A laboratory denied accreditation has 14 days from notification to appeal in writing to the COLA Board of Directors Appeals Committee.

When Complaints are Made to COLA

COLA will investigate all complaints made against COLA accredited laboratories. Complaints deemed to present a potential risk of harm to patients or employees, as well as those deemed to be potentially serious, are investigated via an unannounced complaint investigation survey. Complaints made up of less serious allegations can be investigated by requesting specific documentation from the laboratory. All labs which have complaints lodged against them will be made aware of the nature of the complaint. Although COLA strongly believes that the laboratory must be made aware when a complaint is received, it will not disclose the complainant's identity to the laboratory.

Depending on the severity of the complaint, COLA may simply request supporting information to evaluate the complaint, or it may schedule a surveyor to conduct an unannounced survey. The unannounced survey will be targeted to evaluate the complaint, unless the surveyor identifies deficiencies that merit a full COLA survey. At the conclusion of its investigation, COLA will send the laboratory a letter indicating the favorable resolution of the complaint, or it will request additional actions be taken by the laboratory to resolve the problem. All investigations will be reported to CMS, and for laboratories accredited by COLA that are affiliated with healthcare systems accredited by The Joint Commission, reported to The Joint Commission.

Complaints Made to Government Agencies

For complaints about COLA accredited laboratories made directly to government agencies, CMS or the state surveying agency may either refer the complaint to COLA or conduct their own investigation. The CMS State Operations Manual instructs state surveying agencies to investigate complaints by means of an on-site survey, by telephone, by letter, or by a documentary review. CMS will not announce on-site complaint investigations.



IN THIS SECTION

Overview: COLA Criteria for Quality Laboratory Performance And Self-Assessment Questions	37
The Criteria and Self-Assessment Follow the Path of Workflow.....	37
About the Self-Assessment Question.....	38
Essential (E) vs. Required (R) Criteria	38
The Criteria Cover 16 Main Evaluation Groupings in the Laboratory Path of Workflow	39
Understanding the Criteria and Completing the Self-Assessment: Helpful Information by Evaluation Grouping.....	40
Organization	41
Facility.....	45
Lab Director Responsibilities	49
Personnel.....	56
Proficiency Testing.....	66
Laboratory Information Systems.....	73
Pre-Analytic.....	75
Analytic – General Requirements Procedure Manual.....	80
Maintenance	83
Verification of Performance Specifications.....	89
Calibration.....	92
Quality Control	96
Waived Testing.....	104
Specialty-Specific Criteria.....	108
Hematology	108
Coagulation	111
Chemistry and Urinalysis.....	113
Microbiology and Subspecialties.....	115
Immunology.....	125
Immunoematolog.....	126
Post-Analytic.....	127
Quality Assessment.....	134
Immunoematology / Transfusion Service.....	140

At a Glance... Criteria and Self-Assessment: What You Need to Do

The COLA Criteria for Quality Laboratory Performance are the COLA standards you must meet to achieve compliance, and ultimately accreditation. They cover 16 primary evaluation groupings, plus Transfusion Services, which may or may not apply to your laboratory.

The Criteria are presented as questions – the questions are used for your Self-Assessment and are the same questions COLA surveyors will use to evaluate your laboratory during the on-site survey.

You evaluate your laboratory's current practices against the requirements for compliance spelled out in the Criteria.

You complete the Self-Assessment, answering “yes” or “no” to each question in sequence, referencing helpful information provided about each evaluation grouping.

You complete the Self-Assessment by using COLAcentral® (after you have submitted your test menu to COLA). COLA will process the data, and provide guidance to help you correct noncompliant criteria before your on-site survey.

Correcting noncompliant criteria before the on-site survey will likely save you time in the accreditation process and your laboratory will realize benefits sooner.

Overview: COLA Criteria for Quality Laboratory Performance and Self-Assessment Questions

Laboratories must meet specific COLA requirements - called the Criteria for Quality Laboratory Performance - to be granted COLA accreditation.

The Criteria for Quality Laboratory Performance are presented for you to learn the COLA requirements and for you to use as questions to perform the Self-Assessment. These questions serve as a guide for your laboratory to improve quality and efficiency in all aspects of laboratory operations, while meeting COLA standards for compliance. The Self-Assessment is intended for completion by the laboratory director and staff in advance of the on-site survey conducted by COLA. The COLA surveyor who visits your laboratory will use the same list of questions to evaluate your laboratory, so performing the Self-Assessment is a great way to prepare. It is also useful as a reference for maintaining compliance between surveys.

The Criteria and Self-Assessment Follow the Path of Workflow

The Criteria are an educational tool that evaluates your laboratory processes through the path of workflow. In the medical laboratory, “path of workflow” is defined as the sequence of activities beginning with the initiation of a request for healthcare services, all the way through the delivery of those services. Simply stated, it represents the path a patient specimen follows as it moves through the laboratory; i.e., test orders and specimen collection and receiving (pre-analytic phase), testing (analytic phase), and result reporting (post-analytic phase). General criteria have impact across all phases of testing. To mirror this path, the COLA Criteria are categorized in order as General, Pre-analytic, Analytic, and Post-analytic.

Do not be surprised if some phases of your laboratory operation do not initially meet the COLA requirements. Take enough time while completing the questions to understand the requirements and make plans to correct noncompliant criteria you identify.

Be sure to consider each test system and every test, and each and every person filling designated positions in the laboratory as you answer the questions. Any partial noncompliance should be answered as a “no.” Only 100 percent compliance in every instance qualifies for a “yes” answer.

It is to your laboratory's advantage to answer “no” to questions for which your laboratory is only in partial compliance, because helpful educational feedback will be sent prior to your on-site survey, if the Self-Assessment is submitted to COLA for review.

Please be as self-critical in your review as possible. Do not be concerned that at survey time your honest responses will bias the surveyor about the operations of your laboratory. The surveyor will not use your self-assessment responses in their evaluation, but the surveyor will see the improvements you have made as a result of your self-assessment activities.

Once all the questions have been completed, either by using the Self-Assessment on COLAcentral® or submitting the forms, COLA will review your answers to determine if your laboratory has any noncompliant criteria. If any noncompliant criteria are indicated, the laboratory director will be sent a letter focusing on the problem areas and describing what actions the laboratory can take to come in to compliance in advance of the on-site survey.

About the Self-Assessment Questions

The Self-Assessment consists of questions covering every aspect of the laboratory operation from specimen collection and handling, to personnel, Proficiency Testing, and Quality Assessment. These questions are followed by additional questions for Transfusion Services, that only apply if your laboratory provides these services.

Section III of the Accreditation Manual contains all of the COLA criteria for all specialties that COLA accredits. However, when the lab accesses the Self-Assessment using COLAcentral®, it will be customized to display only those criteria that are applicable to the lab based on testing specialties performed in your lab. This is why it is important to have your test menu up to date prior to completing the Self-Assessment in COLAcentral®.

Essential (E) vs. Required (R) Criteria

COLA's Criteria for Quality Laboratory Performance define specific requirements for the laboratory. You'll notice in the Criteria that each question is classified as *Essential (E)* or *Required (R)*, defined as follows:

Essential criteria are laboratory practices so essential to testing that if these criteria are not followed, laboratory results may be of questionable clinical use and patient care may be negatively impacted.

Required criteria are COLA requirements that are recognized as important to good laboratory practice, but a single noncompliance would not seriously jeopardize the clinical utility of test results. Clinical utility can be impaired, however, if several required criteria are not followed. Required criteria expand on the Essential criteria by delineating specific policies, activities, and documentation the laboratory must have to be accredited.

As you review each of these groupings, keep in mind that in addition to overall documentation of laboratory functions and activities, some groupings have their own specific documentation requirements, such as personnel, quality control, Proficiency Testing, and quality assessment.



QUICK TIP

The Criteria for Quality Laboratory Performance and the Self-Assessment questions are one and the same.



Evaluation groupings abbreviations key

The Criteria use abbreviations to identify the evaluation groupings for each question.

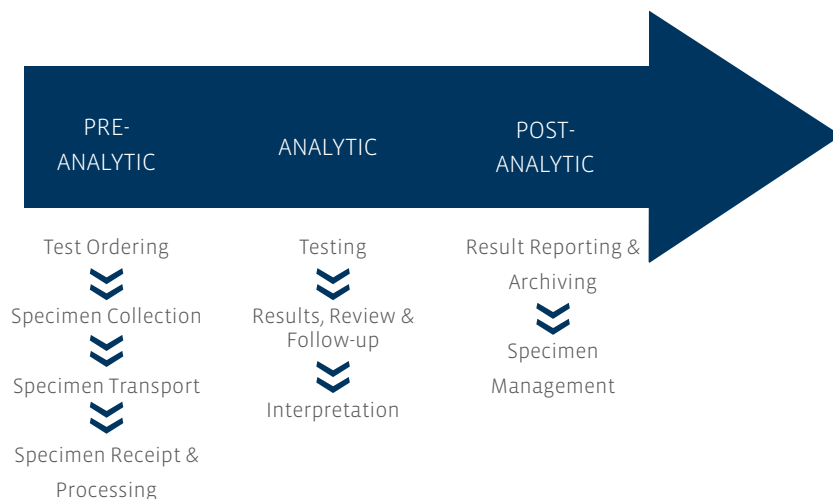
EXAMPLE: QA 19 R means “Quality Assessment Question 19, Required Criteria.”

To facilitate your use of the Criteria, here’s the abbreviation for each evaluation grouping, in sequence of how they are published:

ORG	Organization
FAC	Facility
LDR	Lab Director Responsibilities
PER	Personnel
PT	Proficiency Testing
LIS	Lab Information Systems
PRE	Pre-analytic
APM	Analytic Procedure Manual
MA	Maintenance
VER	Verification of Performance Specifications
CA	Calibration
QC	Quality Control
WAV	Waived Testing
HE	Hematology
CO	Coagulation
C	Chemistry and Blood Gases
U	Urinalysis
M	General Microbiology
SU	Susceptibility
BA	Bacteriology
MYCB	Mycobacteriology
MYC	Mycology
PA	Parasitology
VI	Virology
SY	Syphilis Serology
IH	Immunohematology
PST	Post-analytic
QA	Quality Assessment
TS	Transfusion Services

The Criteria Cover 17 Main Evaluation Groupings In the Laboratory Path of Workflow

Laboratory Path of Workflow



COLA’s Criteria for Quality Laboratory Performance are organized into 17 evaluation groupings based on the laboratory processes shown below. The sequence of the criteria follows the design of the overall laboratory operation and specifically the path of laboratory workflow. The criteria are used to determine if a lab meets COLA standards for accreditation.

- Organization
- Facility
- Lab Director Responsibilities
- Personnel
- Proficiency Testing
- Lab Information Systems
- Pre-analytic
- Procedure Manual
- Maintenance
- Verification of Performance Specifications
- Calibration
- Quality Control
- Waived Testing
- Specialty-Specific Criteria
- Post-analytic
- Quality Assessment
- Transfusion Services

Understanding the Criteria and Completing the Self-Assessment: Helpful Information About Each Evaluation Grouping

The following pages of this Manual provide background information on each of the evaluation groupings covered by the Criteria for Quality Laboratory Performance. You are urged to read the explanatory information for each grouping to help you understand the requirements and perform the Self-Assessment.

EVALUATION GROUPING:

Organization

Organization is one of the General laboratory systems that has impact across the entire path of workflow.

The laboratory is greatly influenced by the goals of the organization. The laboratory director and management team should define the mission, purpose, and goals for the laboratory, determine the functions performed by the laboratory, and layout the structure and resources allocated to accomplish them.

Activities evaluated in this group include:

- Determining the extent of laboratory services you will provide
- Maintaining valid CLIA certificate and/or state licenses
- Establishing testing specialties under the scope of your CLIA certificate and/or state licenses
- Defining a process for handling changes and notification of changes to appropriate regulatory entities
- Establishing policies for maintaining confidentiality and handling complaints
- Implementing a mechanism for identifying and reporting device safety issues to the FDA
- Creating and maintaining a comprehensive procedure manual to cover all activities within the scope of the laboratory system



Look for “Evaluation Grouping” Headings

To help you find specific criteria easily throughout this section, each group of the Criteria for Quality Laboratory Performance begins with the words “Evaluation Grouping” followed by the name of the specific grouping. For example, to the left you see the first listing: Evaluation Grouping: Organization. In this case, “Organization” is the name of the evaluation grouping and refers to the organizational structure of the laboratory.

ORG 1 E

Does your laboratory have the appropriate CLIA certificate and/or state license required based on the complexity of testing performed and is the certificate and license current?

All laboratories that perform testing on human specimens for the purpose of assessment of health, diagnosis, monitoring treatment or impairment of health are subject to federal CLIA requirements. Laboratories must apply to CMS to obtain the proper CLIA certificate based on the complexity of testing conducted by the laboratory.

You must know the classification of your laboratory testing in order to determine personnel and quality control requirements. Call the manufacturer of the instrument or kit test if you are unsure of its classification. If you perform any high complexity tests, the personnel performing the tests must meet the education and experience requirements for high complexity testing.

Individual states can also have state licensure requirements that must be met. State requirements vary considerably. Each laboratory must determine whether any existing state laboratory laws apply to them.

For instance, some states require all labs to be licensed; others require only hospitals or reference labs to be licensed. Still others may not require the laboratory to be licensed but may have personnel licensure requirements; these are covered under PER 2 – personnel qualifications. Many states and localities have specific requirements for communicable disease reporting and hazardous waste management. While these must also be adhered to, they are not part of COLA's assessment. For assistance in determining whether your state has specific regulations with which the lab must comply, please consult your state's website.

ORG 2 E

Do you only test in the specialties for which you are accredited by COLA, or do you use a CLIA-approved accreditation organization or state survey agency for those specialties for which COLA is not approved by CLIA?

To comply with CLIA regulations, the laboratory may not test in specialties for which it is not certified. Call COLA if you think you may be doing tests for which you are not certified.

ORG 3 R

Do you notify COLA in writing within 60 days of any additions or deletions to your test menu and verify that all new regulated analytes are enrolled in a COLA-approved PT program, and that COLA is designated to receive the results from your PT program?

ORG 4 R

Does the reference laboratory to which you refer specimens possess a valid government certificate to perform the tests that you refer to them?

Ask your reference laboratory to send you a copy of their certificate(s).

ORG 5 R

If you accept referred specimens: Do you make available to your clients a list of methods including performance specifications (accuracy, precision, sensitivity, and specificity), interfering sub-stances, and reportable range of results?

You should have the performance specifications of the tests you perform available should a referring client wish to see them.

ORG 6 R

If you accept referred specimens, do you provide clients with updated information whenever you make changes in your laboratory procedures that could affect the results of the tests?

ORG 7 R

Do you have systems in place to maintain the confidentiality of patient information throughout all phases of the testing process?

Confidentiality of patient information, including patient charts and reports, must be protected throughout pre-analytical, analytical and post-analytical phases of the testing process in accordance with federal and state laws. This includes patient charts as they follow the patient throughout an office visit. This must address electronic and/or hardcopy results (as applicable).

ORG 8 R

Does the laboratory maintain a posted notice to employees, advising them how to report concerns related to the safety and quality of patient testing as performed in this facility?

Complaints regarding laboratory services may be recognized and brought forward by internal customers (such as employees) or external customers (such as patients, or referring clinicians). This criterion focuses on the communications to employees regarding the protocol for reporting concerns that could impact the safety or quality of patient testing. This should be addressed in your Quality Assessment Program so that an investigation can be conducted, and corrective actions taken as necessary.

As your accrediting agency COLA takes complaints made against an accredited laboratory seriously. Your notice should encourage staff to use internal protocols to report potential safety or quality issues pertaining to patient testing. It should also inform employees that the issue may be reported to COLA, if it is not addressed or cannot be resolved through internal channels.

COLA has created a notice that accredited labs can post to meet this requirement. It can be obtained by downloading the notice from the COLA website (www.colacentral.com). The notice should be posted in a conspicuous place, where it can be easily seen by employees.

ORG 9 R

Does the laboratory have a procedure for the FDA voluntary reporting of device-related adverse events?

Every laboratory should have a procedure for voluntary reporting device-related adverse events to the FDA. Device-related adverse events cause serious patient injuries that are life threatening; or result in permanent impairment of a body function or permanent damage to a body structure; or necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Inaccurate test results produced by an In vitro device (IVD) and reported to the health care professional may lead to medical situations that fall under the definition of serious injury as described above, and therefore are reportable events.

Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, labeling, reagents or calibration; or to user error (since the latter may be related to faulty instrument instructions or design).

For additional information, please visit COLA's website (www.colacentral.com).

ORG 10 R

Does the laboratory have documented education of its personnel in the FDA procedure for voluntary reporting of device-related injuries and // or malfunctions?

Laboratory documents training of staff on the FDA voluntary reporting procedures.

ORG 11 E

Do you have a procedure manual?

Every laboratory should have a complete procedure manual that includes test procedures as well as general laboratory policies. For further help with how to write a procedure, see COLA LabGuide 1 – “Contents of a Procedure Manual.”

ORG 12 R

Does the procedure manual include all tests offered by the laboratory?

Don't forget to include those tests performed by manual methods (e.g. urine sediment examination).

ORG 13 R

Is the procedure manual easily accessible to your personnel?

It is important for laboratory personnel to have easy access to the procedure manual. Staff should not rely on memory as this may lead to erroneous results if the procedure isn't remembered correctly.

ORG 14 R

Do personnel follow all procedures as written in the procedure manual?

If you have someone from outside your practice prepare your procedure manual, make sure the procedures reflect the way your personnel actually perform the tests in your laboratory.

*»NOTE: A copy of the manufacturer's package insert or operator's manual, or a copy of a textbook description of the test procedure may be used in the manual if it provides the information required under **Section APM**. Any components of the test procedure that are not addressed by the manufacturer, such as the steps to be taken when a test system is malfunctioning, must be written into the individual procedure. You can also maintain a general policy statement in the laboratory for these procedures.*

ORG 15 R

Are all test procedures reviewed, approved, and signed annually by the laboratory director?

If there have been no changes, the Laboratory Director may delegate the annual review to a qualified designee.

Does the laboratory director sign and date (ORG 16 through 18):

ORG 16 R

Each new procedure prior to use?

ORG 17 R

Any changes in procedure prior to implementation of the change?

ORG 18 R

The entire manual if he/she is a new director?

The laboratory director is responsible for approving and signing procedures in these circumstances (ORG 16-18). This responsibility cannot be delegated.

ORG 19 R

Are procedures date when they are initially put into use and when they are discontinued?

This will be helpful to you in determining when a procedure can be discarded.

ORG 20 R

Are discontinued procedures kept for at least two years beyond the discontinued date?

EVALUATION GROUPING:

Facility

Facility is one of the General laboratory systems that has impact across the entire path of workflow. This section refers to the physical layout of your laboratory. Ensure that work space, equipment, facilities, and supplies are sufficient enough so that the required volume of work can be performed with accuracy, precision, efficiency, and safety.

The facility criteria are intended to ensure that your laboratory can provide prompt, reliable reporting of results. This group of questions also focuses on universal precautions, personal protective equipment (PPE), and facility safety practices.

FACILITY

FAC 1 R

Does your laboratory have adequate space, ventilation, and utilities necessary for conducting all phases of the testing process in order that patient care is not compromised?

The laboratory should be located in a convenient, yet out of the way place in the facility. It should not be a heavy traffic area and it should not be an area where patients must pass through on a routine basis.

You must ensure access to the necessary utilities, (power, environment, water, drainage and disposal systems) are sufficient for the work and equipment used in the laboratory.

If your lab handles biological or caustic chemicals, a proper ventilation system is essential for employee and patient safety. The type of caustic or biological materials handled will determine the requirements necessary for adequate protection of patients and safety. The laboratory may consult MSDS sheets, OSHA requirements, and other laboratory texts to determine the type of precautions required.

FAC 2 R

Is the laboratory constructed, arranged, and maintained to minimize contamination of patient specimens, equipment, instruments, reagents, materials and supplies?

Based on the volume and type of testing performed, the laboratory should evaluate the workspaces available to perform various laboratory functions. To the extent possible, designate specific areas for various tasks to minimize accidental spills, mix-ups or contamination.

FAC 3 R

Is the laboratory organized to ensure uni-directional workflow if molecular amplification procedures are performed?

Uni-directional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process. The purpose of moving in a single direction is to prevent cross-contamination. This must include separate areas for specimen preparation, reagent preparation, amplification, and product detection. Molecular procedures based on nucleic acid testing are growing in popularity for the detection of infectious diseases (HIV, HBV, HCV, CMV, Chlamydia trachomatis, Neisseria gonorrhoeae, and Mycobacterium tuberculosis). Common procedures that involve amplification processes include polymerase chain reaction (PCR), strand displacement amplification (SDA), transcription mediated amplification (TMA) and ligase chain reaction (LCR). This list is by no means complete. Laboratories performing testing based on any of these principles will need to evaluate workflow processes in accordance with their test system and manufacturers requirements.

FAC 4 R**Have steps been taken to prevent sporadic power fluctuations?**

Many newer laboratory instruments have internal surge protectors; check your operator's manual to see if this is the case. If it does not contain an internal surge protector, a surge protector can be obtained from your local hardware or electronics store. Also, check your operator's manual to see whether your instrument requires a dedicated line. If this is the case, nothing else should be plugged into the circuit where your instrument is attached to the power source. Any other instruments or even a light or radio could cause enough power fluctuation to affect the calibration of the instrument.

FAC 5 R**Is there a proper type fire extinguisher in working condition and/or a fire blanket in the laboratory or within 50 feet of the lab?**

Make sure the extinguisher's gauge shows that it is properly charged and/or is inspected on an annual basis.

FAC 6 R**Does your laboratory have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs?****FAC 7 R****Are refrigerators which are used for storing reagents, controls, or specimens free of improper materials, such as food or unsealed volatile materials?**

Remember that glucose tolerance test beverage and oral polio vaccine are consumed by patients and should not be stored with specimens or test reagents.

FAC 8 R**Do all centrifuges have lids to prevent aerosols?**

Plexiglas covers are available for desktop centrifuges with conical rotating heads. Ask your laboratory supplier for details or request that your reference laboratory supply you with a cover if they provided the centrifuge. If a centrifuge is only used for urine specimens, this requirement does not apply.

FAC 9 R**Are measuring devices, such as dilutors and volumetric, serological, and semi-automated pipettes of certified accuracy?**

Disposable measuring devices should be of certified accuracy: this is printed on the pipette itself. Non-disposable pipettes, such as volumetric, should be of certified accuracy (CLASS "A"). Semi-automated pipettes frequently come with calibration collars and instructions for use. Dilutors should also be checked as part of routine preventive maintenance. Semi-automated pipettes without a calibration mechanism should have their calibration verified at least once per year.

FAC 10 R**Are damaged pipettes discarded?**

Damaged pipettes have broken tips and/or blurred or lost markings.

FAC 11 R**Does the laboratory follow proper procedures for the use and maintenance of pipettes and pipetting devices?**

The laboratory must choose whether to utilize disposable or re-useable pipetting devices depending on the requirements of the test system. Reusable pipettes require either individual tips to be used to minimize contamination or require other cleaning or rinsing procedures between samples to minimize contamination. Disposable devices should only be used once.

FAC 12 R**Have potential toxic, biologic and/or radiologic hazards been identified and are all these substances properly stored and safely disposed?**

You should have a safety manual or a safety section in your procedure manual, addressing the general policies established in your laboratory for handling toxic and biohazardous materials in the laboratory.

FAC 13 R**Are all disposable sharps, needles, and syringes safely discarded in a separate, marked container for the protection of employees, patients and custodial staff?**

It is important for the laboratory to utilize appropriate devices to prevent potential injury to employees and patients alike. Needles and other sharps must be disposed of in a "sharps container" which is clearly marked "biohazard."

Ideally, needles should be self-sheathing and the sharps container is one which can be operated with one hand. Sharps containers must be closable, puncture resistant, and leak proof on the sides and bottom. They must be located as close as possible to the immediate area where sharps are used.

Needles should not be removed from syringes or blood tube holders and they should not be recapped, bent or sheared. Recapping needles is only permitted when required by a specific medical procedure, and in this case, a one-handed "scoop" technique must be used.

If blood is collected in examining rooms, a sharps container should be in each room. If younger patients may be seen by the practice, this container should be out of reach of children. As an alternative, a portable phlebotomy tray including a sharps container may be used.

FAC 14 R**Do you have a bloodborne pathogens exposure control plan?**

This is an OSHA requirement and needs to be a written document. You should comply with OSHA requirements for handling bloodborne pathogens, and state and/or local requirements for disposal of hazardous waste. You can obtain information from OSHA by calling (202) 693-1999. This is OSHA's general information number. OSHA requires that all employees receive annual training in this plan.

FAC 15 R

Are protective clothing, gloves, masks, eye protection devices, and face shields available to personnel performing tasks that require the use of such articles?

OSHA requires protective clothing to be provided and laundered by the employer. These items of clothing are not to be worn outside of the work area, nor taken home for laundering. Gloves must be worn when performing phlebotomies and when handling containers of regulated body fluids. Masks, goggles, and/or face shields must be made available anytime there is a likelihood of an employee being splashed by blood or another contaminated substance (e.g., when emptying biohazardous waste, cleaning up a spill, etc.)

FAC 16 R

Are gloves worn when performing phlebotomies?

See commentary for FAC 15.

FAC 17 R

Are universal precautions observed when handling specimens?

Universal precautions are now required by OSHA; it is no longer an employee option. Employers can be fined if they do not require that their employees follow universal precautions when they come in contact with blood or other regulated bodily fluids.

FAC 18 R

Are eating, drinking, smoking, and applying cosmetics prohibited in the laboratory?

FAC 19 R

Is mouth pipetting prohibited in the laboratory?

Make sure that pipette bulbs are available for employee use. Even distilled water should not be mouth pipetted.

EVALUATION GROUPING:

Laboratory Director Responsibilities

The laboratory must be under the direction of a qualified individual, and that individual must fulfill all the responsibilities of the Laboratory Director. CLIA prohibits a Laboratory Director from directing more than five nonwaived laboratories.

The Laboratory Director is responsible for the overall operation and administration of the laboratory, and for assuring compliance with all applicable regulations. The Laboratory Director must meet education and experience requirements (see PER evaluation grouping) to hold the position, and must meet all of the responsibilities associated with the position, including ensuring that there are sufficient personnel with adequate experience and training to conduct the work of the laboratory. He or she must also ensure that every position in the laboratory is filled by an individual qualified to hold the position and able to perform the tasks required of the position.

The requirement for the laboratory to be under the direction of a qualified individual is not automatically met simply because the director meets the education and experience requirements described in the PER evaluation grouping. The individual must also demonstrate that he or she is providing effective direction over the operation of the laboratory. When determining whether the director responsibilities are being met, the surveyor will consider deficiencies found in other areas, such as facility administration; proficiency testing; and general, pre-analytic, analytic, and post-analytic systems.

Some responsibilities of the Lab Director may be delegated to a qualified individual. However, it remains the responsibility of the Lab Director to ensure that all delegated duties are properly performed.

If qualified, the Laboratory Director may hold other required positions in the laboratory. If so, he or she must also meet those responsibilities.

Laboratory Director Responsibilities (Moderate and High Complexity)

The Laboratory Director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following:

General Responsibilities

- Must be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed.
- Direct no more than five labs.
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide an environment that is safe from physical, chemical, and biological hazards.
- Ensure compliance with all applicable regulations.
- Verify that all of the following responsibilities are properly performed. Procedural Responsibilities
- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing.
- Ensure test methods selected have the capability of providing quality results.
- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.
- Ensure that reports of test results include pertinent information required for interpretation.
- Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.
- Ensure that an approved procedure manual is available to all personnel.
- Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

Procedural Responsibilities

- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing.
- Ensure test methods selected have the capability of providing quality results.
- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.
- Ensure that reports of test results include pertinent information required for interpretation.
- Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.
- Ensure that an approved procedure manual is available to all personnel. Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

Personnel Responsibilities

- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results.
- Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to verify that they maintain competency to:
 - Process specimens,
 - Perform test procedures, and
 - Report test results promptly and proficiently.
- Whenever necessary, identify the need for remedial training or continuing education to improve skills.
- Maintain a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance, or results reporting; and whether consultant or director review is required prior to reporting patient test results.
- In a high complexity laboratory, ensure that a general supervisor provides on-site supervision of high complexity test performance by minimally qualified testing personnel.

Proficiency Testing (PT) Responsibilities

- Ensure that the laboratory is enrolled in an approved Proficiency Testing (PT) program.
- Ensure that PT samples are tested in the same manner as patient samples.
- Ensure that PT results are returned on time to the PT program.
- Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory.
- Ensure that PT samples are tested according to COLA and CLIA regulations prohibiting referral of specimens and communication of results.

Quality Control and Quality Assessment Responsibilities

- Ensure that Quality Control and Quality Assessment programs are established and maintained to identify failures in quality as they occur.
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. Ensure that patient test results are reported only when the system is functioning properly.

LDR 1 E**Does the Laboratory Director meet the General Responsibilities of the position?**

General Responsibilities

- Must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.
- May direct no more than five nonwaived labs.
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide an environment safe from physical, chemical, and biological hazards.
- Ensure compliance with all applicable regulations.

How can this responsibility be met?

- *Make sure there is enough counter and storage space for testing. Ensure that electrical power, including shock and power surge protection, is adequate.*
- *Assure that your laboratory is complying with the Hazard Communications standard – see US Code of Federal Regulations 29CFR 1910.1200, at:
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099
and the Bloodborne Pathogens standard – see US Code of Federal Regulations 29CFR 1910.1030, at:
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051.*
- *Take appropriate safety measures, including the use of warning labels, and the provision of personal protective equipment.*
- *Assure that environmental conditions (temperature, humidity, etc.) that can affect testing are being monitored and acted upon in your laboratory.*
- *Review, become familiar with, and assure compliance with the CLIA regulations and the COLA criteria.*
- *Review, become familiar with, and assure compliance with any state or local laboratory regulations that apply to your laboratory.*
- *Get involved in the survey process (work with your laboratory staff to complete the Self Assessment before the survey) and take advantage of the education that a surveyor can provide.*
- *Participate in the exit conference at the conclusion of your laboratory inspection.*

LDR 2 E**Does the Laboratory Director meet the Procedural Responsibilities of the position?**

Procedural Responsibilities

- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing.
- Ensure test methods selected have the capability of providing quality results.
- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.
- Ensure that reports of test results include pertinent information required for interpretation.
- Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.
- Ensure that an approved procedure manual is available to all personnel.
- Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

How can this responsibility be met?

- *Work with your laboratory staff to select test systems carefully and monitor their performance in the pre-analytic, analytic, and post-analytic phases of testing.*
- *Work with suppliers and manufacturers to select test methods with proven accuracy that meet your needs.*
- *Verify that the manufacturer's stated performance characteristics are achieved in your lab.*
- *Assure that Quality Control is performed, that it is regularly reviewed by appropriate technical staff to monitor the test method's performance over time, and that when problems are identified, they are corrected prior to reporting patient test results.*
- *Ensure that personnel follow the manufacturer's directions and use good laboratory practices.*
- *Make sure that test reports include all necessary information that could be significant for interpreting the results. For example:*
 - *Patient sex and age,*
 - *Time of last dose, for medication levels,*
 - *The source of the specimen,*
 - *If the patient was fasting.*
- *Be available to discuss laboratory results with laboratory clients (ordering physicians or patients).*
- *The procedure manual must include a procedure for every test performed and be available to laboratory personnel.*
- *Review, approve, date and sign all procedures before they are put into use. Review, approve, date and sign all new procedures and all changes to procedures.*
 - *A new Lab Director must review, approve, date and sign all procedures as soon as they become the Lab Director.*
 - *Annual review of procedures can be delegated to a qualified individual, as long as there are no changes to the procedures.*

LDR 3 E**Does the Laboratory Director meet the Personnel Management Responsibilities of the position?**

Personnel Management Responsibilities

- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, accurately perform tests, and report test results.
- Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to verify that they maintain competency
 - To process specimens,
 - Perform test procedures, and
 - Report test results promptly and proficiently.
- Whenever necessary, identify the need for remedial training or continuing education to improve skills.
- Maintain a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance or results reporting; and whether consultant or director review is required prior to reporting patient test results.
- In a high complexity laboratory, ensure that a general supervisor provides onsite supervision of high complexity test performance by minimally qualified testing personnel.

How can this responsibility be met?

- *Be involved in the hiring of personnel and make sure they have the necessary education and experience.*
- *Evaluate the volume of testing performed, the number of testing personnel, and turn-around-times to ensure adequate personnel are available.*
- *Develop job descriptions for all laboratory personnel and keep them updated.*
- *Assure that personnel are provided with adequate training for the duties and testing that they will be performing.*
- *Verify that all personnel have documentation of the necessary education and experience.*
- *Assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process and keep the list of assigned duties current.*
- *Establish standards for personnel performance and assure that personnel competency reviews are completed every six months for first year & annually thereafter. This should include observation of personnel as they perform procedural steps in the pre-analytic, analytic and post-analytic phases of testing.*
- *Require and provide remedial training when needed.*
- *Provide opportunities for continuing education.*
- *High complexity directors must employ a general supervisor and that person must be onsite when high complexity testing is performed by individuals that require supervision as described in §493.1489(b)(5) of the CLIA regulations.*

Individuals who require supervision qualified for high complexity testing via Sec. 493.1489(b)(5), which states:

“i) Until September 1, 1997--

A) Have earned a high school diploma or equivalent; and

B) Have documentation of training appropriate for the testing performed before analyzing patient specimens.

Such training must ensure that the individual has--

1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

2) The skills required for implementing all standard laboratory procedures;

3) The skills required for performing each test method and for proper instrument use;

4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

5) A working knowledge of reagent stability and storage;

6) The skills required to implement the quality control policies and procedures of the laboratory;

7) An awareness of the factors that influence test results; and

8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

ii) As of September 1, 1997, be qualified under Sec. 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995”

LDR 4 E**Does the Laboratory Director meet the Proficiency Testing Responsibilities of the position?**

PT Responsibilities

- Ensure that the laboratory is enrolled in an approved Proficiency Testing (PT) program.
- Ensure that PT samples are tested in the same manner as patient samples.
- Ensure that PT results are returned on time to the PT program.
- Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory.
- Ensure that PT samples are tested according to COLA and CLIA regulations prohibiting referral of specimens and communication of results.

How can this responsibility be met?

- *Select an approved PT provider that meets your needs.*
- *Maintain continuous enrollment in a PT program.*
- *Make sure testing personnel understand all the rules and requirements for testing PT samples, and the importance of submitting results on time.*
- *Review, initial, and date all PT reports and evaluate your lab's performance.*
- *Require staff to investigate any unacceptable results and any results that do not reflect the lab's performance (see COLA criterion PT 10) and to take corrective action when needed. Review, approve, initial, and date all PT failure investigations conducted by your staff.*
- *Retain documentation of all PT activities for 2 years.*

LDR 5 E**Does the Laboratory Director meet the Quality Control and Quality Assessment Responsibilities of the position?**

QC and QA Responsibilities

- Ensure that Quality Control and Quality Assessment programs are established and maintained to identify failures in quality as they occur.
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly.

How can this responsibility be met?

- *Develop comprehensive policies and procedures for the performance and acceptability of Quality Control.*
- *Assure that appropriate technical staff review QC regularly to confirm that policies and procedures are being followed by all staff.*
- *Assure that appropriate technical staff review and initial Quality Control results, graphs, and problem logs regularly, and verify that appropriate remedial actions are performed and documented.*
- *Develop and implement a Quality Assessment plan that monitors the overall quality of the total testing process and ensures continuous improvement of the laboratory's performance and services.*
- *Assure that QA reviews are effective at identifying and preventing errors, and that corrective actions are followed up for effectiveness.*
- *Establish written policies and procedures for evaluating performance specifications. Specify the remedial actions to take when they are not met.*
- *Make sure laboratory policy states that patient results are not to be reported when the test system is not functioning properly (i.e., QC is out of range, etc). Ensure that all staff follow this policy.*

EVALUATION GROUPING:

Personnel

Personnel is one of the General laboratory systems that has impact across the entire path of workflow. The questions in the Personnel grouping address the human resources in the organization. These questions look at the relationship between functional duties and employee performance in the workplace.

It is important to review the actual process of managing personnel to ensure there is clarity of roles and responsibilities. When there is a lack of communication among individuals with shared responsibility, there is often a breakdown in the process, which could ultimately affect quality and/or safety.

COLA's personnel standards for accreditation are identical to federal and state personnel standards. The laboratory director and staff must meet all applicable federal and state personnel requirements necessary to qualify to hold their position and to perform their job functions in the laboratory.

The director has the responsibility to ensure that there are sufficient personnel with adequate experience and training to conduct the work of the laboratory. He or she must be sure that every position in the laboratory is filled by an individual qualified to hold the position and able to perform the tasks required of the position. CLIA prohibits a laboratory director from directing more than FIVE laboratories.

In some circumstances, one person can fill every position if they are qualified and adequately trained. For example, in a moderate complexity laboratory, the physician director could also be the clinical consultant, the technical consultant, and the testing person.

Personnel: Requirements and Test Complexity

Personnel requirements vary according to the complexity of testing performed in the laboratory. There are two categories of test complexity: waived tests and non-waived tests. For personnel qualifications, non-waived testing is separated into high complexity tests and moderate complexity tests which include provider performed microscopy procedures (PPMP). To decide which personnel are required for your level of testing, determine your complexity of testing by consulting information from your instrument and test kit manufacturers, or check the Food and Drug Administration (FDA) website for the list of test classifications.



What Types of Personnel Do You Need in Your Laboratory?

A. Waived Testing: Laboratories performing only “waived” tests have no personnel standards – anyone can perform waived tests.

B. Provider-Performed Microscopy Procedures: “PPMP” tests may be performed by:

- MDs, Dos, or DPMs
- Dentists
- Nurse Practitioners
- Nurse Midwives These are the only providers who are qualified to perform these tests under a PPMP Certificate. In addition, those practitioners performing PPMP testing must be licensed by the state, if applicable. Individuals qualified to perform moderate complexity testing are qualified to perform these microscopic tests under a Certificate of Accreditation or a Certificate of Compliance.

C. Moderate Complexity Testing: Laboratories performing moderate complexity tests require the following personnel positions:

- Laboratory Director
- Clinical Consultant
- Technical Consultant
- Testing Personnel

D. High Complexity Testing: Laboratories performing high complexity tests require:

- Laboratory Director
- Clinical Consultant
- Technical Supervisor
- General Supervisor
- Testing Personnel If your laboratory performs even one high complexity test, high complexity personnel requirements apply to laboratory director, technical supervisor, general supervisor, and any testing personnel who perform high complexity tests.

Personnel: Required Positions

Use the following guidelines to identify which personnel positions are needed in your laboratory. For more detailed information, refer to the Personnel Requirements charts for specific educational, licensure, and experience requirements for each moderate and high complexity personnel position.

Personnel: Qualifications, by Position

Please use the following chart to ensure that all personnel in your laboratory are qualified to hold their positions.



QUICK TIP

For more information about laboratory personnel, see the LabUniversity® course Laboratory Personnel Requirements at www.labuniversity.org.

PERSONNEL REQUIREMENTS

NOTE: All individuals must have all required state licenses for all positions held – pertains to the state where the lab is located

MODERATE COMPLEXITY LABORATORIES

DIRECTOR	TECHNICAL CONSULTANT	CLINICAL CONSULTANT
<ol style="list-style-type: none"> 1. Licensed MD/DO/DPM, AND certified in anatomic or clinical pathology, OR lab training or experience consisting of 1 year directing or supervising non-waived tests, OR Beginning 09/01/1993, have earned at least 20 CME credits in laboratory practice addressing director responsibilities, OR training equivalent to 20 CME credits obtained during medical residency. 2. Doctoral degree in laboratory science AND certified by an HHS-approved Board, OR have 1 year experience directing or supervising non-waived testing. 3. Master's degree in lab science AND 1 year lab training or experience AND 1 year of experience supervising non-waived testing. 4. Bachelor's degree in lab science AND 2 years lab training or experience AND 2 years experience supervising non-waived testing. 5. Prior to 02/28/1992, qualified as Director under state law or Medicare lab regulations. 	<ol style="list-style-type: none"> 1. Licensed MD/DO/DPM AND certified in anatomic or clinical pathology OR 1 year lab training or experience in non-waived specialty/subspecialty of service. 2. Doctoral or Master's degree in laboratory science AND 1 year lab training or experience in the non-waived specialty / subspecialty of service. 3. Bachelor's degree in laboratory science AND 2 years lab training or experience in the non-waived specialty / subspecialty of service <p>NOTE: "Training or experience" in specialties and subspecialties can be acquired concurrently.</p>	<ol style="list-style-type: none"> 1. Licensed MD/DO/DPM. 2. Doctoral degree in laboratory science AND board certified in specialty/subspecialty of service. <h4>TESTING PERSONNEL</h4> <ol style="list-style-type: none"> 1. Licensed MD/DO/DPM 2. Doctoral, Master's, Bachelor's, or Associate's degree in laboratory science 3. High School graduate or equivalent AND completed military Medical Lab Specialist (50 week) course. 4. High School graduate or equivalent AND documentation of training at the present facility for testing performed.

HIGH COMPLEXITY LABORATORIES

DIRECTOR	TECHNICAL SUPERVISOR	GENERAL SUPERVISOR
<p>1. Licensed MD/DO/DPM AND certified in anatomic or clinical pathology OR 1 year of lab training during medical residency OR 2 years experience directing or supervising high complexity testing.</p> <p>2. Doctoral degree in laboratory science AND certified by an HHS-approved board OR prior to 02/24/2003, served as Lab Director AND 2 years lab training or experience AND 2 years experience supervising or directing high complexity testing.</p> <p>3. Prior to 02/28/1992, qualified as Lab Director under state law or Medicare lab regulations.</p> <p>TESTING PERSONNEL</p> <p>1. Licensed MD/DO/DPM.</p> <p>2. Doctoral, Master's, Bachelor's or Associate's degree in laboratory science.</p> <p>3. Have education equivalent to an Associate's degree AND graduated from a clinical laboratory training program OR have 3 months experience in each specialty of high complexity testing performed.</p> <p>4. Prior to 04/24/1995, High School graduate or equivalent AND graduated from an HHS-approved lab training program OR completed military Medical Lab Specialist (50 week) course.</p> <p>5. Prior to 04/24/1995, High School graduate or equivalent AND documentation of training for high complexity testing AND if training before 01/19/93, on-site supervision is required when high complexity testing is performed.</p> <p>NOTE: Must also provide documentation of training at the present facility for testing personnel</p> <p>For Blood Gases: If not qualified above: Bachelor's or Associate's degree in respiratory therapy, pulmonary function, or cardiovascular technology</p>	<p>Specific qualifications are required for each specialty or subspecialty.</p> <p>For Microbiology subspecialties – bacteriology, mycobacteriology, mycology, virology, and parasitology:</p> <p>1. Licensed MD/DO/DPM or PhD AND certified in clinical pathology OR 1 year lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service.</p> <p>2. Master's degree in laboratory science AND 2 years lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service.</p> <p>3. Bachelor's degree in laboratory science AND 4 years lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service.</p> <p>For Immunology, Chemistry, Hematology, or Radiobioassy:</p> <p>1. Licensed MD/DO/DPM or PhD AND certified in clinical pathology OR 1 year lab training or experience in the high complexity testing specialties performed</p> <p>2. Master's degree in lab science AND 2 years lab training or experience in the high complexity testing specialties performed.</p> <p>3. Bachelor's degree in lab science AND 4 years lab training or experience in the high complexity testing specialties performed.</p> <p>For Immunoematology:</p> <p>Licensed MD/DO/DPM AND certified in clinical pathology OR 1 year lab training or experience in immunoematology testing.</p> <p>CLINICAL CONSULTANT</p> <p>1. Licensed MD/DO/DPM.</p> <p>2. Doctoral degree in lab science AND board certified in specialty/subspecialty of service...</p>	<p>1. Qualified Lab Director or Technical Supervisor of high complexity testing.</p> <p>2. Licensed MD/DO/DPM, or have a Doctoral, Master's, or Bachelor's degree in lab science AND 1 year laboratory training or experience in high complexity testing.</p> <p>3. Qualified as Testing Personnel for high complexity testing AND at least 2 years laboratory training or experience in high complexity testing.</p> <p>4. Previously qualified as General Supervisor on or before 02/28/1992.</p> <p>5. Prior to 09/01/1992, served as General Supervisor of high complexity testing AND prior to 04/24/95 completed military Medical Lab Specialist (50 week course) AND had at least 2 years lab training or experience in high complexity testing OR graduated from an HHS-approved lab training program AND had at least 2 years lab training or experience in high complexity testing</p> <p>6. Prior to 09/01/1992, served as General Supervisor of high complexity testing AND have a high school diploma or equivalent AND more than 10 years experience in high complexity testing including at least 6 years supervisory experience from 09/01/1982 to 09/01/1992.</p> <p>7. Prior to 09/01/1992, served as General Supervisor of high complexity testing and prior to 01/01/1994: passed an HHS approved technical proficiency exam given between 03/01/1986 and 12/31/1987 AND have 6 years lab training or experience with 2 years in high complexity testing specialties.</p> <p>For Blood Gases: if not qualified above:</p> <p>1. BA/BS in respiratory therapy, or cardiovascular technology AND 1 year training or experience</p> <p>2. AA/AS related to pulmonary function AND 2 years training or experience.</p>

Personnel: Responsibilities, by Position

Please use the following information to ensure that all personnel in your laboratory are meeting the responsibilities that their positions entail.

Position: Laboratory Director (Test Complexity: Moderate and High)

The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following:

General Duties

- Verify that all of the following responsibilities are properly performed if delegated
- Must be accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed
- May direct no more than five labs
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide a safe environment from physical, chemical, and biological hazards

Procedural Duties

- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing
- Ensure test methods selected have the capability of providing quality results
- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method
- Ensure that reports of test results include pertinent information required for interpretation
- Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions
- Ensure that an approved procedure manual is available to all personnel.
- Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results

Personnel Duties

- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results
- Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to verify that they maintain competency to:
 - Process Specimens
 - Perform test procedures
 - Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills
- Have a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance, or results reporting; and whether consultant or director review is required prior to reporting patient test results
- Ensure that a general supervisor provides on-site supervision of high complexity test performance by certain testing personnel

Proficiency Testing (PT) Duties

- Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program
- Ensure that PT samples are tested in the same manner as patient samples
- Ensure that PT results are returned on time to the PT program
- Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory
- Ensure that PT samples are performed according to COLA and CLIA regulations prohibiting referral of specimens and communication of results Quality Control Duties
- Ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system
- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. Patient test results are reported only when the system is functioning properly

Position: Clinical Consultant (Test Complexity: Moderate and High)

The clinical consultant renders opinions concerning the diagnosis, treatment, and management of patient care, and:

- Is available to provide consultation to the laboratory's clients
- Is available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations
- Is available for consultation and communication with the laboratory's clients on matters related to the quality of test results reported and their interpretation concerning specific patient conditions
- Ensures that reports of test results include pertinent information required for specific patient interpretation

Position: Technical Consultant (Test Complexity: Moderate)

Position: Technical Supervisor (Test Complexity: High)

The technical consultant or technical supervisor is responsible for technical and scientific oversight of the laboratory. This person is not required to be on-site at all times, but must be available to provide consultation either on-site, by telephone, or electronically. In addition, the technical consultant/supervisor:

- Selects test methodologies appropriate for the clinical use of the test menu
- Verifies test procedures performed and establishes the laboratory's performance criteria, including accuracy and precision of each test and test system
- Enrolls the laboratory in an approved PT program commensurate with services offered
- Establishes a quality control program appropriate for the testing performed
- Establishes the acceptable levels of analytic performance, and ensures these levels are maintained throughout the testing process
- Resolves technical problems and ensures remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications
- Ensures patient test results are not reported until all corrective action has been taken and the test system is functioning properly
- Identifies training needs and ensures testing personnel receive regular in-service training
- Evaluates the competency of all testing personnel on an ongoing basis
- Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation.

Position: General Supervisor (Test Complexity: High)

The general supervisor:

- Is accessible to testing personnel at all times testing is performed to provide on-site, telephone, or electronic support
- Provides day-to-day supervision of personnel performing high complexity testing
- Must be on-site to provide direct supervision when high complexity testing is performed by certain individuals
- Monitors test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained
- Fulfills certain responsibilities if delegated by the lab director or technical supervisor, such as:
 - Resolving technical problems and ensuring remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications
 - Ensuring patient test results are not reported until all corrective action has been taken and the test system is functioning properly
 - Providing orientation to all testing personnel
 - Annually evaluating and documenting the performance of all testing personnel

Position: Testing Personnel (Test Complexity: Moderate and High)

Testing personnel are responsible for specimen processing, test performance, and for reporting test results, and should only perform those tests that are authorized by the laboratory director and that are within the individual's skill level as determined by education, training or experience, and technical abilities. Testing personnel must:

- Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting, and maintaining records of patient results
- Maintain records which demonstrate that proficiency testing samples are tested in the same manner as patient specimens
- Adhere to the laboratory's quality control policies and documenting all QC activities, instrument and procedural calibrations, and instrument maintenance
- Follow the laboratory's policies whenever test systems are not within the laboratory's established acceptable levels of performance
- Be able to identify problems that may adversely affect test performance or reporting of test results and either correct the problem or notify the appropriate supervisor
- Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications
- Only perform high complexity testing under the on-site direct supervision of a general supervisor, if required by personnel qualification requirements



Screening Candidates for Positions:

! =Here's What to Evaluate

When hiring laboratory personnel, the director should evaluate the individual's **training and experience and qualifications** to hold the position by:

- Reviewing education, credentials, and references
- Reviewing test performance experience
- Assessing the laboratory worker's knowledge of laboratory operations



Competency Assessment: Individual Must be Able To Perform Assigned Tasks.

The evaluation of each staff member must assess the competency of the individual to fulfill the duties and responsibilities of their position. This includes assessment of actual test performance and interpretation of results.

Personnel: Job Descriptions

A written job description is a required for all personnel because it aids employees in understanding what is expected of them and defines their authority to act and/or make decisions in various circumstances. It should include a list of tasks and responsibilities for all phases of laboratory testing (general, pre-analytic, analytic, and post-analytic). This is a good place to identify the level and type of testing each employee is qualified to perform.

Personnel: Training

The director must document personnel training in the personnel files of laboratory staff, including his or her own file. Continuing education is also important for staff, and can be provided by one-on-one instruction, in-service programs, training on instruments or kits by the manufacturer, or formal continuing education activities such as LabUniversity®. Some states have specific continuing education requirements for laboratory personnel in order to meet licensure requirements.

Personnel: Competency Assessment

This is not simply a traditional "employee review" of the individual's initiative, work ethic and interpersonal skills. The focus of competency assessment is to carefully evaluate the individual's ability to perform assigned tasks — according to the defined process and procedure — to assure accurate and reliable laboratory results.

Include all staff in the competency assessment process, ranging from personnel involved in specimen collection and processing to those responsible for supervision and compliance. Competency assessments should occur every six months for the first year and annually thereafter for all testing personnel, supervisors, and technical consultants. Methods of competency assessment must include, but are not limited to:

- Direct observation of routine patient test performance;
- Monitoring the recording and reporting of test results;
- Review of intermediate test results or worksheets;
- Direct observation of instrument maintenance;
- Blind sample testing (such as Proficiency Testing); and
- Assessment of problem solving skills.

Competency of testing personnel is commonly assessed through direct observation, monitoring reporting of results, monitoring of records, observation of instrument maintenance, proficiency testing performance (or testing of blind or split samples), and assessment of problem solving skills. To ensure quality test performance in your laboratory, all testing personnel should be familiar with:

- The test name and purpose of the test
- The equipment necessary to perform the test
- Specimen collection and handling
- Preparing, labeling, using, and storing reagents, standards, and controls
- Special requirements, safety procedures, etc.
- Step-by-step performance of the test calibration or standardization
- Quality control procedures and criteria defining unacceptable results for controls. Recommended corrective action when control limits are not met
- Necessary calculations, when appropriate
- Derivation of results, i.e., how to use direct readouts, calibration curves, calculations from a standard, etc.
- Reference ranges (normal range) and alert values
- Quality assessment procedures

PERSONNEL

PER 1 R

Is there a written job description for each employee that describes individual duties and responsibilities?

A written job description aids employees in understanding what is expected of them and defines their authority to act and/or make decisions in various circumstances. It should include a list of tasks and responsibilities for all phases of laboratory testing (pre-analytic, analytic, and post analytic). This is a good place to identify the level and type of testing each employee is qualified to perform.

PER 2 E

Are all required positions for your laboratory filled and are the individuals filling those positions qualified by education and experience?

For detailed information on education and experience requirements and eligibility pathways for all CLIA defined positions, refer to the COLA Accreditation Manual, Section III, "Personnel Requirements" chart or to COLA LabGuide 4 "Personnel for Nonwaived Testing." If your state has more stringent personnel standards or licensure requirements than CLIA and COLA, the laboratory director must ensure that all personnel meet the more stringent requirements.

PER 3 R

Does the personnel file contain documentation of the person's education and experience that qualifies them for the position they hold in the laboratory?

CLIA specifies the education and experience that an individual must have to fill the required positions. Documentation should verify the highest level of education that qualifies the individual for the position held in the laboratory. Appropriate documents include a copy of a diploma or degree, or a transcript indicating date of graduation. These should be kept in the personnel file for review by the COLA surveyor. Résumés, etc., are sufficient for documenting years of experience. Foreign credentials must be evaluated by an acceptable credentialing agency for US equivalency. Language translation of the documents is not sufficient to meet this requirement.

PER 4 E

Does each laboratory employee adequately fulfill the responsibilities for the position(s) they hold?

For detailed information on Laboratory Director Responsibilities, refer to the LDR evaluation grouping.

For detailed information on responsibilities for other CLIA defined positions, refer to the COLA Accreditation Manual, Section III, "Personnel: Responsibilities, by Position" or refer to COLA LabGuide 4 "Personnel for Nonwaived Testing."

PER 5 R

Does your director or Technical Supervisor/Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation?

This is not simply a review of the individual's initiative, interpersonal relationships, and work ethic although these are important attributes. The focus of this process is the individual's ability to perform assigned tasks according to defined process and procedure to assure accurate and reliable laboratory results. The review must address the competency of each individual to fulfill the duties and responsibilities of their position including assessment of actual test performance and interpretation of results.

All staff are to be included in this process from personnel involved in specimen collection and processing to those responsible for supervision and compliance. Evaluations should occur semi-annually for the first year and annually thereafter for all testing personnel, supervisors and technical consultants.

Methods of competency assessment must include, where applicable:

- *(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;*
- *(ii) Monitoring the recording and reporting of test results;*
- *(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;*
- *(iv) Direct observation of performance of instrument maintenance and function checks;*
- *(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
- *(vi) Assessment of problem solving skills.*

PER 6 R

Do the personnel reviews include the person's continuing education?

COLA believes that continuing education is essential for competent laboratory staff.

EVALUATION GROUPING:

Proficiency Testing

Proficiency Testing is one of the General laboratory systems that is used to assess the entire path of workflow.

Overview

Proficiency testing (PT), like the COLA Accreditation program, is an independent, external assessment providing feedback on your laboratory performance. PT is one way of comparing your laboratory's results with other laboratories using the same instrument or kit. All COLA-accredited laboratories must enroll and participate in an approved PT program.

COLA does not provide proficiency testing samples as part of its services. COLA monitors the laboratory's performance in proficiency testing as part of the accreditation process.

Proficiency testing measures the laboratory's ability to analyze specimens of unknown value and obtain accurate results within an established range. If the laboratory has adequate instrument maintenance, personnel training, and quality control procedures, proficiency testing should be successful. Unsuccessful proficiency testing is an indication of possible problems in these areas, and a warning that patient testing may not be accurate.

Proficiency testing must be performed on all regulated analytes. The approved PT providers offer the majority of the regulated analytes tested in laboratories. If certain regulated analytes are not available from your primary PT provider, you should enroll with an additional PT program.

COLA strongly recommends that laboratories perform PT on unregulated analytes as an added measure of external quality assessment. If the lab is not enrolled in PT for unregulated analytes, then some form of external comparison, such as split specimen analysis, must be performed twice yearly.

And because COLA believes that Waived Testing is also important to patient care, COLA now has an **educational enforcement** criteria requiring PT on waived testing. See the Waived Testing Evaluation Grouping, WAV 10.



You Must Enroll in an Approved PT Program

The laboratory must enroll in an approved proficiency testing (PT) program as a requirement of COLA accreditation. For practices with multiple locations, each of which has its own CLIA number, each laboratory location must enroll separately in proficiency testing and independently perform its own proficiency testing.

Ensuring Proper Performance of Proficiency Testing

Proficiency testing specimens must be tested in the same fashion as patient specimens. Retain written documentation of every step of testing to verify that PT specimens have been handled properly.

Specifically:

- Test PT samples with the regular patient workload using routine methods
- Test PT samples the same number of times as routine patient specimens
- **There may be no inter-laboratory communication of results** until after the date the laboratory must report PT results to the program for the testing event
- **The laboratory must not send PT samples or portions of samples to another laboratory** for analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its PT samples to another laboratory for analysis will have its CLIA certification revoked for at least one year. COLA will deny accreditation to a lab if it intentionally refers a PT specimen to another laboratory for analysis. COLA will not accept reapplication for one year
- **Any laboratory receiving PT specimens from another lab for testing must notify CMS of the receipt of those samples.** Failure to notify CMS may result in revocation of the laboratory's CLIA certificate. COLA will deny accreditation to a lab if it intentionally accepts a PT specimen from another laboratory for analysis. COLA will not accept reapplication for one year
- The individual testing the PT specimen and the laboratory director must sign an attestation statement that PT specimens are tested in the same fashion as patient specimens
- Retain all PT records for two years

Proficiency Testing Grading Criteria

So that the laboratory complies with CLIA, COLA uses the same proficiency testing enrollment requirements and grading criteria as the federal government.

Laboratories are required to achieve 80% correct results for most analytes, specialties, and subspecialties, in order to receive a passing score for that event.

The only exceptions are ABO/Rh and compatibility, in which the lab must achieve a score of 100% for each PT event. COLA monitors your laboratory's performance for each analyte and specialty through our PT Tracking System.

Laboratories that do not attain the minimum satisfactory score for an analyte, subspecialty, or specialty for a single testing event, or multiple testing events, are subject to additional requirements.

Make sure to determine the root cause and immediately implement corrective action for any PT challenges that do not meet the provider's expected results. Repeated unsuccessful PT can lead to a mandatory six-month cease testing order for the analyte, specialty, or subspecialty.

Unsatisfactory PT Performance

If your laboratory fails a single testing event, it receives a performance score of “unsatisfactory” for that analyte. Your laboratory must take appropriate action to identify the problem, correct it, and document the corrective action in the laboratory records. These records will be reviewed by the COLA surveyor during document review at your laboratory’s on-site survey.

Unsuccessful PT Performance

If your laboratory fails to achieve a minimum satisfactory score in two consecutive, or two of three consecutive testing events for an analyte, specialty, or subspecialty, it receives a performance score of “unsuccessful” for that analyte, specialty, or subspecialty. You must seek consultation to remedy the causes of the failures and you must provide COLA with written documentation of the corrective action taken.

COLA monitors each accredited laboratory’s performance for regulated analytes and specialties and will contact the laboratory in the event of PT failure with information on corrective action and troubleshooting tips.

Cease Testing for Proficiency Testing Failures

As a result of the CLIA regulations, proficiency testing failures are a major concern to laboratories. COLA may require a laboratory to cease testing the failed analyte, specialty, or subspecialty until the laboratory can demonstrate compliance with COLA accreditation criteria. Laboratories that demonstrate consecutive unsuccessful PT performance will be directed to cease testing the analyte, specialty, or subspecialty for a minimum of six months, and the laboratory demonstrates satisfactory performance for two consecutive PT testing events.

A COLA laboratory can voluntarily withdraw from patient testing until it corrects its PT performance. The laboratory is not given a time penalty, nor is its accreditation jeopardized by the failure of a single specialty.

Unregulated Analytes

As a valuable quality assurance measure, COLA expects laboratories with PT performance failures for an unregulated analyte to document in the laboratory records the corrective action taken to remedy the problem.

Waived Testing

COLA also has an **educational enforcement** criteria that requires PT on waived tests (WAV 10). This means that COLA will cite your laboratory if you are not enrolled in PT for waived testing. But the citation will be educational only, and will not count as a “deficiency” citation. COLA believes that waived testing is important to patient care, and therefore quality in the performance of waived testing should be a standard in your lab.

PT 1 E**Have you been continuously enrolled, and have you successfully participated in one or more CMS-approved Proficiency Testing (PT) program(s) for all regulated analytes?**

Enrollment is required for all regulated analytes on your test menu. See the list of approved PT programs. You should authorize your PT program to send your PT data to COLA by submitting the PT Data Release Form to your PT provider(s). This form serves as confirmation that COLA may receive your PT data. Please complete this form and forward to your PT provider and also send a copy to COLA if you have not done so.

PT 2 E**For each regulated analyte tested in your laboratory, do you perform and report PT results to the PT program for all events, unless you have been granted an exemption by the PT program and COLA for voluntarily ceasing to test an analyte?**

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if:

- *Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;*
- *The laboratory notifies COLA and the proficiency testing program, within the time frame for submitting proficiency testing results, of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and*
- *The laboratory participated in the previous two proficiency testing events.*

PT 3 E**If your laboratory tests any regulated analyte(s) for which compatible proficiency testing samples are not offered by a COLA-approved PT program, do you perform and compare the results of external split-specimen testing on at least five specimens twice a year?**

When compatible PT specimens are available for regulated analytes, the laboratory must participate in PT. COLA-approved PT programs strive to provide PT samples for the most commonly performed laboratory methods and maintain sufficient participants to ensure peer groups are available for providing graded results. At times this can be quite a challenge especially as new technologies are available in the marketplace.

When the laboratory is choosing its PT provider, it is important to verify that specimens provided will be compatible with the methods in use in the laboratory. If the current PT provider does not offer a compatible specimen for any regulated analyte/test system, the laboratory must investigate whether a suitable sample can be obtained from another PT provider.

If it is not possible to obtain a compatible specimen from any PT Provider for a regulated analyte, the laboratory must perform Split Specimen analysis at least twice per year, testing 5 samples each time. The laboratory should try to obtain and test samples that span the reference range typically seen in the patient population. Ideally there should be specimens among the 5 that have low, normal, and high values or positive and negative values as applicable.

It is the laboratory's responsibility to check with the various PT providers each year to determine if a compatible specimen might now be available. When compatible PT specimens are available for regulated analytes, the laboratory must participate in PT.

PT 4 R

For each unregulated analyte tested in your laboratory that you have not enrolled in a COLA-approved PT program, do you perform and compare the results of external split-specimen testing on at least five specimens twice a year in periodic intervals?

Proficiency testing or split specimen testing with another laboratory is an acceptable check. For split specimen testing, five specimens should be split twice a year. The laboratory must determine the acceptable variation permitted when comparing results on the same sample. The laboratory should consider the amount of variation that represents a clinically significant difference for the analyte being tested. Most often the acceptable variation is stated as plus or minus a percentage or constant factor. (For example ± 10 percent or ± 0.2 .) Refer to COLA LabGuide 9— “Split Specimen Analysis.”

PT 5 R

Do you follow the same procedures for testing PT samples as you do for patient samples?

PT specimens should be treated just like patient specimens—e.g., if a patient specimen is routinely run once, the PT specimen must be run once. In addition, the person who performs PT testing should vary if more than one person normally performs the test on patients. (For instance, the supervisor should not be the only person who performs testing on PT specimens; all persons who perform testing on patients should take a turn at performing PT testing.) Notify your PT program prior to the cut-off date for result submission of any problems with PT specimens or lab accidents with your PT specimens. The PT program is obligated to provide replacement samples for specimens not received on time or for “problems” such as samples received in a condition that renders them unacceptable for testing. Notify your PT program and COLA, in writing, of any incorrect grading in final reports.

PT 6 E

Does your laboratory policy prohibit communication with another laboratory to discuss PT results, for both regulated and unregulated analytes, prior to the cut-off date for submission of test results for that event?

No communication is allowed prior to the cut-off date for submission of test results for that event.

PT 7 E

Does your laboratory policy prohibit sending any PT samples to another laboratory for analysis?

This includes PT for regulated, unregulated, waived, and non-waived tests. Sending PT samples to another laboratory to be tested is a direct violation of the CLIA regulations and will result in loss of your CLIA certificate.

PT 8 R

Are all PT results reviewed and evaluated by the laboratory director or other qualified designee in a timely manner?

Be sure to document this review by dating and initialing. In order to be effective and to provide the laboratory time to take any required corrective action, the review should be completed within 30 days.

PT 9 E

When PT results are unsatisfactory, do you evaluate the results and take appropriate corrective action?

For most tests, unsatisfactory performance is defined as a score of <80% for any analyte in a single testing event. For ABO, RH typing, and compatibility testing, a score of <100% is considered unsatisfactory performance. Any unsatisfactory performance must be investigated to determine the root cause, and corrective action must be taken and evaluated to prevent recurrence of the problem. Be sure to document your evaluation and corrective actions, and maintain these records as part of your PT documentation.

COLA recommends that each laboratory perform an evaluation and take corrective action for any individual PT challenge that does not fall within the expected range established by the PT provider. This is especially important if you have less than 100% scores on an analyte on consecutive events. This may help you identify a problem and make corrections before that analyte has an unsatisfactory PT event.

PT 10 E

Does your laboratory verify the accuracy of any analyte, specialty, or subspecialty that is assigned a PT score that does not reflect the accuracy of the laboratory's actual test performance?

The laboratory must carefully review graded PT reports received from its PT provider. There are cases where although the laboratory performed and reported PT results, these results may not have been scored or evaluated for accuracy or the laboratory may have received scores that do not truly reflect laboratory performance.

This frequently occurs as a result of one of the following situations:

- *The PT program assigns an artificial score of 100% with a comment that results were not evaluated due to lack of a peer group or lack of consensus within the peer group.*
- *The PT Program assigns an artificial score of 0% due to nonparticipation, such as when a. the laboratory did not test the samples (due to oversight, instrument problems, reagents on backorder, etc.) b. the laboratory fails to submit test results; or c. the results were submitted after the cutoff date for submission.*

When such a situation occurs the laboratory must perform and document its own verification of accuracy for the analyte, specialty, or subspecialty affected. The laboratory may compare its performance against the stated target and allowable range of the PT specimen as defined in the participant summary available from the PT provider.

In some cases this "self grading" may enable the laboratory to demonstrate acceptable performance. In other cases, the laboratory will have to take additional steps to verify the accuracy of its results, such as conducting split sample analysis or other external assessment.

There are a number of methods that may be used to conduct external accuracy verification. The Laboratory Director should determine the best method considering the analyte and methodology in use. Some manufacturers have established special programs just for their users.

If analytes are consistently not graded due to lack of a peer group (at least 10 participants using the same instrument or method) the laboratory should seek assistance from their PT provider. This is not uncommon when a laboratory is using an older methodology or very new technology. In both of these instances the total number of laboratories performing the same method is too small to enable analysis. In such cases the laboratory may need to consider updating its methodology or consulting the manufacturer to see if a user group program might be available for comparison.

**Repeated scores of 0% for failure to participate may result in a cease testing order for the analyte, specialty or subspecialty. Be sure to inform the PT provider if you are unable to perform testing, prior to cutoff date to avoid receiving an automatic score of 0%.*

PT 11 R

When graded PT results are unsuccessful, do you seek consultation to remedy the causes of failure, and/or undertake additional training of personnel if this is the cause of the failure?

Unsuccessful PT performance is defined as receiving unsatisfactory scores for an analyte, subspecialty, or specialty in two consecutive PT events or two out of three PT events.

PT 12 E

Do you cease patient testing for specified analytes when required by COLA until you have successfully completed the reinstatement process?

Does your PT record keeping include: (PT 13-18)

Check the PT records for each of these elements. If the laboratory is a new start-up and has not performed PT as yet, mark PT 13-18 as N/A.

PT 13 R

How the PT specimen is handled, prepared, processed, and reported?

PT 14 R

All PT test records, such as instrument tapes and logs?

PT 15 R

A copy of the attestation form signed by the director and the testing personnel?

PT 16 R

An indication of the review of the graded PT results by the director as well as the supervisory and testing personnel?

PT 17 R

Corrective actions taken as a result of all PT failures?

PT 18 R

Are all PT records retained for a minimum of two years?

EVALUATION GROUPING: Laboratory Information Systems (LIS)

Laboratory Information Systems (LIS) is one of the General laboratory systems. If your laboratory uses an LIS, it has impact across the entire path of workflow, from test orders to test reports. More and more laboratories are finding that an LIS is essential in achieving efficient laboratory operations and functions. An LIS is a computer-based laboratory data system. There are specific requirements for using and maintaining a laboratory information system.

LABORATORY INFORMATION SYSTEMS

A Laboratory Information System (LIS) is an electronic based laboratory data system. If your lab uses a Laboratory Information System (LIS), it is important to have written policies and procedures that describes for your staff how the LIS is utilized.

You may want to address the following questions as you develop policy and procedures: • What functions does it perform? • Are there step by step instructions for staff? • Who is responsible for various functions, operation, and maintenance of the LIS? • How will data be stored, maintained, and retrieved?

• What precautions are in place to protect equipment and data? The laboratory should evaluate computer processes periodically as part of its Quality Assessment Program.

LIS 1 R

If the laboratory has a computer or Laboratory Information System (LIS) used to input, store, or retrieve data in relation to activities performed in the pre-analytic, analytic, or post analytic phase of testing; is there a written procedure manual available to staff?

If a laboratory uses a computer or LIS, it should have a comprehensive procedure manual for its use, describing how data is input, handled and stored, how the system is maintained, and how the systems integrity is protected.

LIS 2 R

Do the procedures for the LIS include:

Procedures should have sufficient detail to enable laboratory staff to perform required tasks.

LIS 2.1

Proper operation of LIS hardware and software?

This includes start up and shut down sequences.

LIS 2.2

Data entry?

LIS 2.3

Generation of work lists, as applicable?

LIS 2.4**Validation of the accuracy of data entry and verification of accuracy of any calculations performed?**

This should be verified initially prior to the LIS being put into use and then assessed periodically as part of a quality assessment review.

LIS 2.5**Approval or acceptance of data manually entered and/or electronically transmitted? LIS 2.6 Data retrieval? LIS 2.7 Reporting of test results? LIS 2.8 Routine maintenance & back-up procedures? LIS 2.9 Troubleshooting and reporting computer failures? LIS 3 R Does the laboratory define which staff members are authorized to perform data entry?**

Not all staff will need access to all data fields. Restriction of access to those fields required for the job description will reduce the potential for erroneous entries. This should be defined in policy based on position. It is advisable to include this in individual job descriptions as well.

LIS 4 E**Does the laboratory have established mechanisms to prevent unauthorized access to the laboratory information system?**

Most systems require a login and secure password to access the system. Some systems have additional security that limits access to certain screens or functions to selected individuals. Some systems will time out if actions are not performed within a set time frame.

The laboratory should assess how the computer is used throughout the path of workflow in the facility to determine areas where security risks may occur and ensure their processes are sufficient to prevent access to unauthorized users.

LIS 5 R**Is there a mechanism that verifies the correctness of manually entered data?**

The verification process should occur prior to final reporting and release of results.

LIS 6 R**Does the laboratory verify that data transferred directly from instruments/microprocessors to the computer system is accurate?**

This should be performed when the LIS is initially put into place and monitored periodically, especially when software changes are made to either instruments or the computer system. This not only includes data transfer from an instrument but also includes transfer of reports from one location to another. This can be included as part of the overall Quality Assessment program.

LIS 7 R**Are electronic test reports stored in a manner permitting complete reproduction on retrieval, including the reference ranges provided at the time of the report, flags, footnotes, and interpretive comments?**



QUICK TIP

Many laboratory errors occur in the pre-analytic phase problems with these activities can have a profound effect on the accuracy and usefulness of test results.

Test requisitions, testing records, and test reports are all required documents for a complete Patient Test Management system. These documents may be paper based or electronic. A single document may serve multiple purposes.

EVALUATION GROUPING: Pre-analytic

As mentioned earlier, the path of laboratory workflow is defined as the sequence of activities that range from initiation of a request for healthcare services, all the way through the delivery of those services. The path of workflow includes general, pre-analytic, analytic, and post-analytic processes. This group of criteria looks at pre-analytic processes, which occur before testing, and includes evaluation of activities such as:

- Test ordering
- Specimen collection and labeling
- Specimen transport
- Specimen receipt and processing

Patient Test Management

Patient test management or test tracking refers to the laboratory system that ensures specimen integrity and positive identification throughout the testing process. It includes such things as the proper

identification of the patient, labeling of specimens to avoid mix-ups, proper storage of specimens, proper tracking of specimens through different stages of testing, test requisitions and reports, and record storage and retention.

Following are some of the most important criteria for the pre-analytic phase of patient test management:

- Instructions for the collection and handling of specimens must be written. These instructions should be included in your procedure manual
- All specimens must be uniquely identified through all phases of testing
- All specimens must be accompanied by a requisition which should include the following information:
 - The patient's name and a secondary identifier
 - Name and address of person requesting the test
 - Contact person for reporting critical values (usually the ordering physician)
 - The name of the test to be performed
 - The date and time of specimen collection
 - Any pertinent clinical information to ensure accurate testing
- Test requisitions must be maintained for at least two years

PRE-ANALYTIC

Test requisitions, testing records, and test reports are required documents. These can be combined into one form or kept as separate forms.

PRE 1 E

Are all specimens accompanied by a requisition?

Test requisitions, testing records, and test reports are all required documents for a complete Patient Test Management System. These documents may be paper based or electronic. A single document may serve multiple purposes.

Often the charge sheet, super-bill or routing slip is used as a requisition. Some facilities elect to combine all the requirements into the design of a single form. The patient's chart may also be used as both the requisition and report form, as long as the chart remains available for laboratory personnel during testing and can be made available at the time of survey.

PRE 2 R

If an oral request for a test has been made, is it followed with a written requisition within 30 days?

This includes in-house ordering, but the requisition may be the written request on the chart, if that is your normal method of requisitioning. Otherwise, a requisition to be kept in the laboratory must be obtained from the ordering physician.

PRE 3 R

If the laboratory accepts referred specimens from another facility: Do you maintain documentation of attempts to obtain a written test request when the initial request was verbal?

Reference laboratories must have written requests for the tests they perform. If that is not possible, you document that you tried to obtain one.

Does the requisition that accompanies the patient specimen contain the following: (PRE 4-9)

PRE 4 R

The patient's name and a secondary identifier?

To contribute to reducing the number of medical errors related to mis-identification of the patient, laboratories need to establish a unique identification system. The system should encompass a means for unique patient identification that links the request, to the specimen, and the report. This can be easily accomplished by using two identifiers, such as patient name and a secondary identifier, such as birth date, medical record number, social security number, barcode, or accession number.

PRE 5 R

The name or unique identification of the legally authorized requestor, the individual responsible for using the tests results, and the address(es) where the report should be sent?

When space is an issue or in some information systems the requesting party's name & address may be assigned a unique code number. In such cases, it is necessary to have a master list that defines the name & address assigned to each code number.

PRE 6 R**The test (examination) requested?**

The term examination is used globally in place of test.

PRE 7 R**Clinical information, including gender, age, specimen source (when appropriate), and other relevant and necessary information?**

Gender and age are important for interpretation of test results to correctly identify the patient reference range. Other relevant and necessary information to include will be dependent upon the test requested. For example:

- *For glucose or lipids, indicate whether the patient is fasting,*
- *For drug levels, indicate the dosage of medication the patient is on and the time the last dose was taken*
- *For cultures, indicate the source of the specimen and whether the patient is already on antibiotics or may have just completed a course of antibiotics.*

PRE 8 R**Space for date and time of primary specimen collection?****PRE 9 R****Space for date and time of receipt by laboratory?**

It is important to know how long it took the specimen to arrive in the laboratory. Many specimens have limited transport or storage time at room temperature. If storage or transport conditions are not followed, this can impact the quality of results obtained. For some practices the time of collection and receipt may be the same. However there are almost always some situations where patients may collect specimens at home or they may be collected at another site and sent to the laboratory. Be sure that, in these situations, staff is aware of the importance of capturing both time of collection and time of receipt.

PRE 10 R**Are ALL test requisitions maintained for at least two years?****PRE 11 R****Do you have written instructions for specimen collection, labeling, preservation, and conditions regarding specimen transport available for your clients and do you provide updates to your clients as they occur?**

You should provide a specimen collection manual to each client who refers tests. This will substantially reduce the chance of invalid results caused by pre-analytic variability.

PRE 12 R**Do you have and follow written policies and procedures for the collection and, handling, transportation and storage of specimens?**

Be sure to include the following items as you develop your policy and procedures:

Collection:

- *Instructions for collecting different types of specimens (finger stick, venipuncture, throat cultures, urines (clean catch, cath, mid-stream, etc...))*
- *Instructions for the proper way to identify the patient and the items to be used in addition to the patient's name to ensure positive identification. (Phlebotomists should say "Please tell me your name" rather than "Are you Ms. Jones?" Some patients may be hard of hearing, in a phase of dementia, or on medications and not always give accurate or appropriate answers.)*
- *Type of collection tube or container and order of collection based on tests requested.*
- *Minimum sample volumes required for specific tests.*

Handling:

- *Criteria for properly mixing tubes with anti-coagulants to prevent clotting*
- *Centrifugation requirements (immediate or delayed)*
- *Accessioning or processing steps required prior to transport, storage, or testing*
- *Timing requirements between collection and testing*

Transportation:

- *Method of transport*
- *Packaging of specimens*
- *Temperature requirements during transport (on ice, room temp)*

Storage:

- *Temperature and time requirements prior to testing*
- *Temperature and time requirements after testing if specimens retained*
- *Proper containers for storage*

The manufacturer's package insert or operator's manual should define specimen handling and storage requirements for each individual test. If your laboratory has additional or different requirements they must be specified.

Many labs elect to write general policies and procedures for specimen collection, handling, and transport then refer to the specific test procedure for more detailed requirements.

PRE 13 R**Is the manual provided by the reference laboratory for specimen collection and handling readily available to personnel involved in the collection of specimens?**

Refer to procedure manual questions related to Pre-analytic.

PRE 14 R**If special tests are performed, do you provide containers with proper preservatives?**

This only applies to laboratories that perform special tests in-house, either for their own patients or for other laboratories. Your reference laboratory should provide containers with proper preservatives to your laboratory for any special tests that you send them.

PRE 15 R**If patients collect their own specimens, are they given written instructions describing how to do so?**

To get the proper specimen, you should have written directions regarding the timing of collections (e.g., for a 24-hour urine, the patient should empty bladder at X o'clock and discard the specimen. Then collect all specimens, including the one voided at X o'clock the next day). Information about medications, fasting, preservation, etc., should be included.

PRE 16 E**Prior to the collection of a patient's specimen, is the patient's identity verified using two separate identifiers?**

Laboratories should be aware of the emphasis in the medical community to reduce medical errors due to misidentification of the patient. One mechanism to affect this is to utilize at least 2 patient identifiers (such as name, birth date, medical record number, or social security number) to verify that specimens are being collected from the correct patient.

Patients may be asked to state their name and birth date as a means of verifying their identity. In hospital settings identity may be verified verbally and/or by confirming the identification with the patient's armband.

PRE 17 R**Are all specimens labeled with a unique patient identifier composed of 2 individual identifiers, and the source of the specimen (when appropriate)?**

To contribute to the reduction of medical errors as a result of mis-identification, it is necessary for laboratories to ensure that all specimens have a unique identification that can be linked to the requisition and report. Using a combination of two identifiers increases the likelihood of catching misidentifications due to common names. Examples of common identifiers include birth date, medical record number, social security number, accession number or barcode.

PRE 18 R**If the patient is not properly prepared for the test according to the laboratory's policy, is the specimen considered unacceptable?**

If you have the ordering physician's permission, it is acceptable to draw a non-fasting specimen for those tests normally requiring fasting specimens as long as the test report is clearly marked "non-fasting specimen used."

PRE 19 E**Are all specimens uniquely identified through all phases of testing?**

When specimens are transferred into sample cups, for example, the sample cups should be marked in some way which identifies which patient's specimen is contained in each sample cup. This may be a numbering system from a work sheet (e.g., each sample run that day is consecutively numbered 1...2...3...4).

ANALYTIC – GENERAL REQUIREMENTS

EVALUATION GROUPING: Procedure Manual

The function of the procedure manual crosses all phases of the path of workflow. The criteria for processes in the Analytic Phase begin here with the analytical aspects of the procedure manual. You will find other requirements that relate to the procedure manual in the Organization, Pre-analytic, and Post-analytic evaluation groupings.

Your laboratory should have a procedure manual for all laboratory operations and all testing performed in the laboratory. The procedure manual should include instructions for performing every test on your lab's test menu, as well as instructions for specimen collection and handling, test reporting, and specimen disposal. The manual should be accessible to all laboratory staff and tests should always be performed as specified in the manual.

Although manufacturers' package inserts or operator manuals may be the basis of the procedure manual, this information should be supplemented with additional information specific to your laboratory. The director should set critical value definitions, if applicable, and reference ranges for the lab based on its patient population, e.g., pediatrics, geriatrics.

Newly-appointed lab directors must review the procedure manual in its entirety. Thereafter, the lab director must annually review the manual, and sign and date the procedure manual cover sheet. When a procedure is revised, it must be approved, signed, and dated by the lab director. When discontinued, it must be dated and retained for two years for historical reference.



The Benefits of a Procedure Manual

The purpose of a procedure manual is to ensure that everyone who performs tests in your laboratory does it in the same manner. It also serves as a reference for your personnel when dealing with unusual situations, and as a training manual for new employees.

ANALYTIC – GENERAL REQUIREMENTS PROCEDURE MANUAL Does the procedure manual include for each test, where applicable: (APM 1-19)

APM 1 R

The test name?

APM 2 (PRE) R

Directions for patient preparation; specimen collection preservation, storage and handling?

These may be included in a separate section (or manual) on specimen collection.

APM 3 (PRE) R

Written instructions for the collection and storage of specimens that a patient would collect themselves?

APM 4 (PRE) R

Criteria for specimen acceptability and rejection of unacceptable specimen?

APM 5 (PRE) R

Instructions for patient and physician notification if a specimen is unacceptable?

When a specimen is unacceptable, the laboratory should document the reason it is unacceptable, whether testing could still be performed but results may be compromised or whether the specimen could not be used and who was notified of the problem.

In some laboratories the patient may be waiting and can easily be re-collected and testing can be performed. In other circumstances it may be impossible to re-collect the specimen. The clinician should be notified so that proper patient follow-up can be assured.

The laboratory will want to monitor the frequency and reason for unacceptable specimens as part of their quality assessment activities. It may be possible to recognize patterns associated with unacceptable specimens that lead to identification of problems that could affect the quality of laboratory results.

APM 6 R

Directions for preparing and storing reagents, solutions, stains, standards and controls?

The directions for preparation should describe the concentration, strength and titer (where applicable) of a reagent, standard, or control. The directions should instruct the individual to ensure all reagents, solutions, stains, standards and controls are properly labeled as to content, date of preparation and expiration. (See MA 1).

APM 7 R**Directions for calibration or standardization, calibration verification and corrective action for failures?**

Directions for calibration and calibration verification procedures should include the following:

- *Identification of the type and concentration of materials to be used,*
- *The number of calibrators required,*
- *Step by step instructions for performing the calibration or calibration verification procedure*
- *Acceptable limits or criteria for interpretation of results*
- *Corrective actions to be taken if the calibration or calibration verification is unacceptable.*

APM 8 R**Control procedures and criteria defining unacceptable control results?****APM 9 R****Corrective actions to take when control or calibration limits are exceeded?****APM 10 R****Step-by-step directions for performing the tests?****APM 11 R****Directions for microscopic examinations?****APM 12 R****Criteria for adequately prepared slides?****APM 13 R****Directions for calculations or interpretation of test results?****APM 14 R****Derivation of test result, i.e., by direct readout, calibration curve, calculation from a standard, etc.?****APM 15 (PST) R****Reference ranges, reportable ranges, and critical values, and when to immediately notify the physician of critical values?**

Miscommunication can be a significant source of errors in the health care environment. For this reason laboratories should utilize a read back requirement whenever providing patient results verbally. This permits the laboratory to verify that there has been no miscommunication.

APM 16 R**The limitations of the test method, including interfering substances?**

Such as lipemia, hemolysis, and other interfering substances.

APM 17 R**Notes, special requirements, safety procedures, literature references, atlases, etc.?**

These items should be included in each procedure, as applicable. Safety instructions should be included in every procedure.

APM 18 (PST) R**How the laboratory reports results (including critical results)?**

Describe how the laboratory provides test results to the ordering practitioner. This may vary depending on whether the patient is waiting for results, or if a critical value is obtained. Include descriptions of how reports are created, distributed, and maintained for future reference.

APM 19 (PST) R**Steps to be taken when a test system is not working or the laboratory is unable to perform the test?**

This procedure should address the proper handling of the patient sample, options available for providing results if needed immediately, and when to communicate the delay in testing to persons utilizing the laboratory services.

EVALUATION GROUPING:**Maintenance**

Maintenance is an activity in the Analytic Phase. The criteria and Self-Assessment questions in the maintenance group focus on instrument function checks, preventive maintenance, temperature and humidity monitoring, reagent storage, and monitoring of other equipment used in specimen preparation or testing.

If proper storage conditions are not maintained, the integrity of reagents, controls, calibrators, and patient specimens cannot be assured. When such events occur the lab should document when the condition was identified and the action taken to correct the problem or relocate the supplies to maintain appropriate storage conditions.

A schedule should be established for the monitoring and upkeep of each instrument, and should be included in your procedure manual.

MAINTENANCE**MA 1 R****Are all reagents, media, standards, and controls properly labeled as to content, preparation, storage requirements, and expiration dates?**

Content includes identity, concentration or strength, and titer where applicable.

MA 2 R**Are specimens, reagents, standards, and controls stored as directed by their manufacturer or other reliable source such as a laboratory textbook?**

MA 3 R

Are reagents included in a kit only used with each other (i.e., not interchanged with another kit with a different lot number or a different manufacturer's kit) unless specifically allowed by the manufacturer?

Many reagent sets or kits are matched by the manufacturer to cause the test to perform optimally. Frequently, control values are based upon the fact that the manufacturer expects you to use the kit as a unit and has calculated the control values accordingly. Therefore, using elements from other kits can cause out-of-control situations to occur, as well as patient testing errors. Kit components from different manufacturers should never be interchanged.

MA 4 R

Are reagents, controls, standards, calibrators, kits, and media properly discarded when they exceed their expiration dates?

MA 5 R

Is reagent grade, deionized, or distilled water available for use if recommended by the manufacturer of test kits, systems, or instruments?

Check test package inserts and operator's manual to learn this information.

MA 6 R

If your laboratory's instrumentation is affected by humidity, is the humidity in the laboratory monitored and corrective action taken if it exceeds the manufacturer's acceptable limits?

To determine if this criterion is applicable to your instrument, check for environmental conditions or specifications in the operator's manual generally found in the section marked "Set Up" or "Installation." Most instruments have an acceptable operating range that is easily met and maintained. However others may have a narrow range, as humidity can affect instrument performance or accuracy and sensitivity of the test method. The more restrictive the range, the more critical it is to monitor humidity when testing is performed.

Frequently this is a building maintenance problem rather than a laboratory problem, but if the humidity does exceed the manufacturer's limits, patient testing should not continue until this problem is corrected. A hygrometer, used for monitoring humidity in percent, may be obtained from many hardware stores, discount stores, and laboratory suppliers. Are temperatures recorded each day of testing and corrective action taken and documented when out of range? (MA 7-13)

Each day of testing temperatures should be recorded. When the temperature is outside of the established range corrective action should be taken to ensure the integrity of the reagents, specimens, instruments and kits. Temperature problems can adversely affect patient results. Always document the actions taken whenever a temperature problem is detected.

MA 7 R

Refrigerators?

MA 8 R

Freezers?

Remember to record temperatures of refrigerators and freezers any time reagents or specimens are stored in them.

MA 9 R**Room temperature?****MA 10 R****Incubators?****MA 11 R****Water baths?****MA 12 R****Dry baths?****MA 13 R****Temperature dependent equipment?**

Some instruments have internal temperature monitoring devices that either refuse to let you perform testing or will not pass the initial self-test when the temperature is out of range. If the instrument gives a readout of the temperature, it should be recorded. This should be one of the daily instrument function checks.

MA 14 R**Have acceptable ranges for temperature been established for each of the above?**

An acceptable range should be established for the above temperature checks by consulting information that comes with the instruments and kits in use in your laboratory. When a temperature is out of range, corrective action should be recorded.

MA 15 R**Are thermometers checked for accuracy at regular intervals?**

Thermometers should be checked at least annually. Thermometers can be checked by comparing them to a National Institute for Standards and Technologies (NIST) standard thermometer. If the thermometer is found to be inaccurate, a correction factor may be applied or a new thermometer acquired when the temperature reading has drifted too much. NIST standard thermometers may be bought from your laboratory supply company. Sometimes hospital laboratories will agree to let you borrow their NIST thermometer. Many reference labs will check your thermometers if you choose not to purchase or borrow an NIST thermometer.

MA 16 R**Does the laboratory take and document all corrective actions taken when storage conditions are not maintained within established limits?**

If proper storage conditions are not maintained, the integrity of reagents, controls, calibrators, and patient specimens cannot be assured. When such events occur the lab should document when the condition was identified, the action taken to correct the problem or relocate supplies to maintain appropriate storage conditions.

MA 17 E**Do you have an instrument maintenance program which includes function checks for each test system?**

A schedule should be established for the monitoring and upkeep of each instrument and should be included in the procedure manual for each test system, including modified tests, tests developed in-house, and when maintenance protocols are not provided by the manufacturer.

MA 18 R**Are function check data accessible for detecting instrument malfunction?**

Many manufacturers provide preprinted forms for the user to document these function checks.

MA 19 R**Are corrective actions, to bring function checks within manufacturer's established limits, taken and documented prior to patient testing?**

If function checks exceed limits that are established by the manufacturer or your laboratory, corrective action needs to be taken and recorded. Documentation should include a description of the problem and all corrective actions performed. This may include documentation of phone calls to technical service (if applicable), copies of instrument printouts, and any applicable service records (if performed by manufacturer service representative). Patient testing should not be performed until the instrument function checks have passed. Refer to the instrument operator manual for assistance in troubleshooting.

MA 20 R**Are manufacturer's directions followed for the maintenance of each instrument or piece of mechanical equipment in the laboratory?**

This criterion addresses the method of maintenance used. Follow the manufacturer's step-by-step directions (i.e., if a certain part should be removed prior to another part, these directions should be followed). These are available in the instrument's operator manual.

MA 21 R**Is preventive maintenance performed and recorded for daily, weekly, monthly, semi-annual, and annual maintenance as required by the manufacturer?**

These requirements are in the instrument's operator manual.

MA 22 R**Are all centrifuges clean and maintained?**

There should not be an accumulation of blood or dirt on the centrifuge. If the centrifuge requires routine maintenance (e.g., brushes checked and/or changed), this should be recorded. When the centrifuge is used as part of the preparation process for a particular test that requires centrifugation at a designated speed, the laboratory should have the revolutions per minute (RPMs) checked at least once per year to ensure that the centrifugation process is adequate for the testing performed.

MA 23 R**Are microscopes properly maintained?**

Microscopes should be cleaned routinely in addition to any scheduled maintenance. It is particularly important to remove any accumulations of immersion oil from the condenser and objectives with a soft cloth and lens cleaner.

Are maintenance logs kept that contain: (MA 24-MA 26)

MA 24 R**Recommended maintenance and function check procedures?****MA 25 R****The frequency of performance of these procedures****MA 26 R****The dates performed and who performed it?**



Verify or Establish?

There are two paths for determination of performance specifications. You will need to select the applicable path based on whether the test method is FDA approved or non-FDA approved.

EVALUATION GROUPING: Verification of Performance Specifications

This activity is part of the Analytic Phase and these requirements apply to all non-waived (moderate or high complexity) methods introduced into the laboratory.

Determination of performance specifications ensures that the test system is operating according to expected performance standards and is capable of producing accurate and reliable results in your laboratory environment, when performed by your laboratory personnel.

Key points about performance specifications:

- The protocol for verification or establishment of performance specifications should be determined by the laboratory director in consultation with the clinical consultant, the technical supervisor, and the manufacturer
- Must be performed in your laboratory by your staff. The manufacturer may assist by providing a protocol and samples for testing
- Data must be reviewed and evaluated by the laboratory director to determine acceptability, prior to initiating patient testing
- Laboratory must document all materials, data, and steps used in the process, and the results and acceptability. Retain for as long as the method is in use plus two years
- Introduction of loaner instruments also requires determination of performance specifications
- Each non-waived instrument's performance must be determined– even if there are multiple instruments of the same make and model

FDA Approved Unmodified Tests

The majority of laboratories will perform FDA approved unmodified tests. The laboratory is required to verify the manufacturer's stated performance specifications for each FDA-approved unmodified test system introduced.

Prior to patient testing, each of the following performance specifications must be verified and documented for each non-waived test or method:

Accuracy: The ability of the test system to obtain the real value of the substance tested

Precision: The ability of the test system to obtain the same result upon repetitive testing

Reference range: The range of values expected for a given population (normal range)

Reportable range: The range, from the lowest to highest value, for which the laboratory can verify the accuracy of the test system. The reportable range cannot exceed the highest or lowest value of the known standard used to verify the test system. Patient results which exceed this range (either high or low) must be reported as greater than or less than the maximum or minimum standard value, or be diluted.

Non-FDA Approved tests (includes modified FDA approved tests)

The laboratory is required to establish performance specifications for each FDA approved but modified, non-FDA approved, or in-house developed test system prior to conducting patient testing. Each instrument's performance must be established – even if there are multiple instruments of the same make and model.

Prior to patient testing, the performance specifications for each FDA approved but modified, non-FDA approved, or in-house developed test system, must be established and documented for:

- Accuracy
- Precision
- Reportable range
- Reference range
- Analytical sensitivity
- Analytical specificity (including evaluation of interfering substances)
- Any other performance characteristics required for accurate test performance



Modifications of FDA Approved Systems

The following items are defined as modifications of FDA approved test systems by CMS:

- Change in specimen handling instructions
- Change in incubation times or temperatures
- Change in specimen or reagent dilution
- Using a different antibody (source, monoclonal-vs.-polyclonal)
- Change or elimination of a procedural step
- Change or addition of detector (conjugate) or substrate
- Change in the solid phase
- Change in the cutoff or method of calculating the cutoff for semi- quantitative assays
- Change in the endpoint or calculation of the endpoint
- Addition of adsorbent
- Change in the strain or antigen in serologic assays
- Changing the calibrator/reference material

VERIFICATION OF PERFORMANCE SPECIFICATIONS

Introduction:

There are 2 paths for determination of performance specifications. The lab will need to determine the applicable path based on whether the test method is FDA Approved or non-FDA Approved. For assistance call or email COLA.

A) Unmodified, FDA approved Test Systems:

The laboratory is required to verify performance specifications for each unmodified, FDA approved test system introduced after 4/24/2003. (VER 1-4 and VER 12).

Verification ensures that the test system is operating according to expected performance standards and is capable of producing accurate and reliable results. Key points to verification of performance specifications:

- The process for verification of performance specifications should be established by the Lab Director in consultation with the Clinical Consultant/Technical Supervisor and the manufacturer
- Must be performed in your laboratory by your staff
- Data must be reviewed and evaluated to determine acceptability by the LD, prior to initiating patient testing.
- Laboratory must document all data collection and validation and retain for as long as method is in use plus 2 years.
- Introduction of loaner instruments and relocation of existing instrument, require verification/re-verification of acceptable performance specifications.
- Each instrument's performance must be verified – even if there are multiple instruments of the same make and model.

Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method: (VER 1-4)

VER 1 R

Accuracy?

When the real value of the substance tested is obtained.

VER 2 R

Precision?

When the same number is obtained upon repetitive testing.

VER 3 R

Reportable patient range?

The range is from the lowest to highest value for which the laboratory can verify the accuracy of the test system. The reportable range for patient results cannot exceed the highest or lowest value of the known standard used to verify the test system. Patient results which exceed this range (either high or low) must be reported as greater than or less than the maximum or minimum standard value unless another procedure has been developed to adjust for specimens beyond the maximum range.

VER 4R

Reference range?

The range of values expected for a given population.

B) FDA Approved Methods Modified by the Lab, Non-FDA Approved Methods, and Test Methods Developed by the Laboratory In-House.

The laboratory is required to establish performance specifications for each FDA-approved but modified, non FDA approved, or in house developed test system prior to conducting patient testing. (VER 5-11). Each instrument's performance must be verified – even if there are multiple instruments of the same make and model.

This ensures that the test system is operating according to expected performance standards and is capable of producing accurate and reliable results. The following are examples of modifications of FDA approved test systems. This list is not all-inclusive, as any deviation from the manufacturer's instructions make the test a modified FDA approved method, and therefore subject to VER 5-11, as well as high complexity personnel requirements:

- Change in specimen handling instructions;
- Incubation times or temperatures;
- Change in specimen or reagent dilution;
- Using a different antibody (source, monoclonal-vs.-polyclonal);
- Change or elimination of a procedural step
- Change or addition of detector (conjugate) or substrate; •
- Change in the solid phase;
- Change in the cutoff or method of calculating the cutoff for semi-quantitative assays;
- Change in the endpoint or calculation of the endpoint;
- Addition of adsorbent;
- Change in the strain or antigen in serologic assays; and
- Changing the calibrator/reference material

Prior to patient testing, have each of the following performance specifications been established and documented for each non-waived test or method: (VER 5 – 11)

VER 5 R

Accuracy?

The real value of the substance tested is obtained.

VER 6 R

Precision?

The same number is obtained upon repetitive testing.

VER 7 R

Reportable range?

The range is from the value of the minimum calibrator to the value of the maximum calibrator. The range is from the lowest to highest value for which the laboratory can verify the accuracy of the test system. The reportable range for patient results cannot exceed the highest or lowest value of the known standard used to verify the test system. Patient results which exceed this range (either high or low) must be reported as greater than or less than the maximum or minimum standard value unless another procedure has been developed to adjust for specimens beyond the maximum range.

VER 8 R

Reference range?

The range of values expected for a given population.

VER 9 R**Analytical sensitivity?**

The lowest level at which a test method can detect the analyte in a specimen being tested.

VER 10 R**Analytical specificity including evaluation of potential interfering substances?**

Analytic specificity is the ability of any test to be substance-specific, measuring the desired analyte (test substance) without detecting other similar or interfering substances that you do not want to measure.

VER 11 R**Any other performance characteristics required for test performance including linearity?****C) Applicable to All Non-Waived Methods**

Prior to patient testing, have each of the following performance specifications been verified and documented for each non-waived test or method. (VER 12-14)

VER 12 R**Have you determined appropriate calibration and quality control frequencies based upon the test system's performance specifications?**

Calibration may be required more often than every six months, depending on the stability of the test system. Criteria CA 2-7 also apply. Monitor the adequacy of these frequencies in providing quality test results as a part of your Quality Assessment Plan.

VER 13 R**Are the established reference (normal) ranges for all patient tests appropriate for the laboratory's patient population?**

As part of the validation process for implementation of non-waived tests and/or methods, the laboratory will need to verify the appropriateness of reference ranges. Consider the patient population served by your laboratory. What factors are present in the patient population that could have an impact on reference ranges, such as age, ethnic background, environmental factors such as elevation, disease states or treatment plans such as oncology and chemotherapy?

Once reference ranges are established, the laboratory will want to monitor the ranges as part of its quality assessment program.

VER 14 R**Does the laboratory take and document all corrective actions taken when test systems do not meet performance specifications verified or established by the laboratory?**

EVALUATION GROUPING: Calibration

This activity is included in the Analytic Phase. Calibration is the process of method standardization. It is performed according to manufacturer's instructions, or as determined by the laboratory during verification or establishment of performance specifications. Calibration is performed by using calibrators (standards) of the number, type, and concentration specified by the manufacturer to actually set parameters in the instrument which will be used as the basis for determining all other test results.

Some tests which do not require calibration are:

- Microscopic tests and manual tests (e.g. manual differentials or microbiology susceptibility tests) not performed using an instrument
- Most Prothrombin Time devices
- Some point-of-care or unit-use devices which are factory calibrated and do not permit user calibration, or calibration is performed internally by the instrument. Such devices are required to have calibration verification performed

Calibration Verification

Calibration verification is intended to confirm that the calibration setting continues to provide accurate results over the reportable range of the test system. It requires a minimum of three (3) samples, (low, mid-point, and high). These samples must have known values and must be tested in the same manner as patients. The results obtained are then compared to the known values and must be within established acceptable limits. If the calibration is stable, the recovered value should match the expected value. If not, troubleshooting, corrective action, and recalibration is indicated.

Calibration verification may be used to verify that a new lot of reagents, a complete change of reagents, or instrument service of critical parts has not altered the calibration. It may also be helpful in troubleshooting unacceptable QC results.

There are some exceptions to calibration verification. For example, for automated cell counters, calibration verification requirements are met if the lab follows manufacturer's instruction for instrument operation and performs a minimum of two (2) levels of QC each day of testing.

CALIBRATION

CA 1 R

For all non waived tests and methods, as applicable, is calibration performed at the frequency recommended by the manufacturer or at the frequency determined by the laboratory if more stringent than the manufacturer? *Calibration is the process of method standardization according to manufacturer's instructions or as determined by the laboratory during verification of performance specifications. This is performed by using calibrators (standards) of the number, type and concentration indicated by the manufacturer to actually set parameters in the instrument as the basis of determining all other test results. Automated cell counters must be calibrated at least every six months.*

EXCEPTIONS:

- *Microscopic tests, and manual tests (e.g. manual differentials or microbiology susceptibility tests) not performed on an instrument do not require calibration.*
- *For most prothrombin time devices, calibration is not practical.*
- *Many point of care or unit use devices are factory calibrated and do not permit user calibration. Such devices are required to have calibration verification performed. Refer to CA 2.*

CA 2 R

Is calibration verification performed, according to the manufacturer's instructions including:

- the number, type and concentration of materials to be used,
- use of materials at low, medium and high values within the reportable range, as determined by the laboratory,
- acceptable limits for calibration verification, once every six months or more often if required by laboratory procedures?

Calibration verification is intended to confirm that the calibration setting continues to provide accurate results over the reportable range of the test system. It requires a minimum of three (3) specimens, (low, mid-point, and high). These specimens need to have known values and should be tested in the same manner as patients. The results obtained are then compared to the known values within manufacturer or laboratory defined limits of acceptability. If the calibration is holding, the recovered value should match the expected value. If not, recalibration is indicated.

This procedure is used to verify that a new lot of reagents, a complete change of reagents, or instrument service of critical parts has not negatively affected the calibration. It may also be used in troubleshooting unacceptable QC results.

If the laboratory's calibration procedures includes 3 or more standards (low, mid point, and high) and is performed at least every 6 months, the requirement for calibration verification is automatically met and the laboratory does not need to take further action in this regard.

EXCEPTIONS

- For automated cell counters, calibration verification is met if the lab follows manufacturer's instruction for instrument operation and performs a minimum of two (2) levels of QC each day of testing.
- For test systems which the laboratory performs three (3) levels of NIST traceable controls (low, mid, and high range) more than once each day of testing and follows manufacturer's instructions, the requirement for calibration verification is met.

CA 3 R

Do you follow accepted methods for calibration and calibration verification for all non-waived test systems?

These instructions can be found in your instrument operator's manual.

CA 4 R

Does the calibration procedure use calibration materials that are traceable to a National Institute of Standards and Technology (NIST) standard?

Most standards which are usually included with the reagents for the test is traceable to a NIST standard, or other national or worldwide standard. Refer to the package insert included with the reagents. If the package insert does not indicate this, check with your manufacturer. Traceable standards are not available for all analytes. You may need to purchase a separate standard set, traceable to a NIST standard, to be used only for calibration or calibration verification.

CA 5 R

Do you perform calibration verification whenever a new lot number or a complete change of reagents occurs, unless it can be shown that such changes do not affect test results?

Exception: Calibration verification does not need to be performed in the case of a lot number change or a complete change of reagents if it can be shown that the calibration of the instrument or method is not affected by these changes. This can be demonstrated by documenting several consecutive instances where there were no adjustments to the calibration needed.

CA 6 E

Do you perform a calibration verification whenever a test system has major preventive maintenance; a critical part is changed; and when controls show shifts, trends, or are out-of-limits; and recalibrate whenever the instrument fails calibration verification?

Service contracts include calibration as part of the preventive maintenance performed by the contractor. If they perform this necessary calibration for you, be sure to retain all relevant documentation.

CA 7 R

Does the laboratory perform and document all corrective actions taken when calibration/calibration verification values are not within established limits?

CA 8 R

Do you recalibrate when quality control shows trends, shifts, or is out of limits, and other corrective action has not remedied the problem?

This is a good troubleshooting and corrective action step to be taken after other corrective actions have been attempted and failed to rectify the problem. Sometimes calibration drifts on instruments between regularly scheduled calibrations and needs to be re-set. Many times recalibration corrects the Quality Control problem. If this doesn't work, it may be time to request a service call for the instrument.

CA 9 R

Do you keep records of all calibration and calibration verification activities including the number, type and concentration of materials used, results obtained, and any adjustments to the calibration?



General QC Requirements...

What Your Laboratory Needs to Do

- Establish a written quality control program that includes information about each test performed. The quality control program should define the frequency, number, and type of controls to perform; acceptable limits for control results; and the corrective actions to take if controls exceed those limits
- Run controls in the same manner as patient specimens
- If controls exceed acceptable limits, do NOT report patient test results until successful corrective action has been taken and controls are within acceptable range
- Testing personnel should review control results daily to detect instrument or procedural failure. Testing personnel should note that they have performed this review
- Record all quality control data for each test performed and plot quantitative results on a quality control graph that permits visual representation of shifts and trends
- Follow manufacturer's instructions for the use of reagents, controls, and kits.
- Unless approved by the manufacturer, do not interchange controls or reagents included in a kit with those of another kit.

EVALUATION GROUPING: Quality Control

This activity is included in the Analytic Phase. Some COLA accreditation criteria are considered general Quality Control (QC) requirements which apply to all non-waived testing, and some criteria only apply to a specialty or subspecialty of testing. All labs must implement the general quality control requirements (QC 1- QC 30), plus any applicable specialty and subspecialty QC requirements.

These QC criteria represent quality laboratory practice. Many of the questions are annotated to help lab personnel understand and apply the criteria. Featured below is an overview of some of the important requirements for a quality control program. Additional information about general control procedures and protocol, as well as specialty-specific quality control requirements are found in the criteria.

Failures in Quality Control

Quality control results must meet your criteria for acceptability prior to reporting patient test results. When QC is performed at the same time as patient testing and the QC results are unacceptable, the laboratory will need to investigate the reason for the unacceptable QC results, and all patient results since the last acceptable control run must be re-evaluated.

Review of Quality Control

The laboratory director is responsible to assure that QC is routinely reviewed to detect and correct potential problems that may impact the accuracy of patient results. This responsibility may be delegated; however the director is ultimately responsible for the performance and quality of the review. QC results should be initialed by the person reviewing them. The QC review should assess the following for compliance with laboratory policy:

- Number, type, and frequency of QC performance
- Acceptability of QC results each day and over time
- Corrective action for out of range results

Alternative Quality Control Procedures

COLA recognizes that, under certain circumstances, the CLIA regulations give laboratories an alternative to performing two levels of external quality control each day of testing. If the laboratory has successfully completed an acceptable study, COLA will permit accredited laboratories an option to use two of the three CLIA-defined Alternative Quality Control (AQC) Procedures (also called Equivalent Quality Control Procedures) in place of external QC each day of testing.

Laboratories that desire to use these procedures must:

- Select the appropriate Alternative Quality Control Procedure,
- Successfully complete the qualifying study, and
- Monitor test and test system performance to include taking corrective action and resuming daily external quality control as indicated in the criteria.

A full explanation of Alternative Quality Control procedures is found in the criteria.

COLA laboratories should now be preparing to phase out EQC and begin learning about the new alternate equivalent QC option, Individualized Quality Control Plans (IQCP). There will be a transition period of approximately two years, estimated to begin in late 2013. Stay tuned to COLA for details.

QUALITY CONTROL

This section addresses requirements related to the control of test methods to assure that immediate and ongoing errors can be detected, and thereby produce accurate and reliable results. All control activities must be documented and maintained in accordance with the record keeping requirements (see PST 27).

QC 1 E

Do you have a quality control program that monitors the complete analytic process for each test performed?

A quality control program must be capable of detecting errors throughout the complete analytic process. This includes errors related to test system components and environmental conditions, as well as operator variance. The quality control program must detect both immediate errors and those that occur over time. A quality control program includes running control materials prior to or concurrent with patient specimens. The program defines the number, type and frequency of controls performed; the established or expected ranges for control values; a process for identification and review of system problems; description of corrective actions to be taken when unacceptable results are obtained; and documentation of all activities.

Does your quality control program define: (QC 2-6)

QC 2 R

The frequency of performing controls?

QC 3 R

The number of controls to perform?

QC 4 R

The type of controls to perform?

Many controls come in various concentrations (e.g., low, normal, high). If the manufacturer does not specify that all levels of control be performed each day of patient testing, then the CLIA requirement of at least two levels applies. If the test system has more than two levels of controls, you should specify the frequency for running each level of control. For example, you may decide that the normal controls should be part of every run and the low and the high controls will be alternated to provide a second control each day of testing. Or you may establish a schedule to rotate the controls run each day.

QC 5 R

The acceptable limits for control results?

For Quantitative controls, statistical parameters (for example mean and standard deviation) for each batch and lot number of control materials must be defined and available. Acceptable limits should be listed on the package insert of the commercially assayed controls for the methodology and instrumentation you are using.

Qualitative controls are positive or negative, reactive or non-reactive, or of graded reactivity (weakly or strongly reactive). This is listed in the package insert as well as on the label of the control material.

QC 6 R

The corrective actions to take if controls exceed those limits?

Patient results may not be reported if the control material does not produce the values or reaction expected. A policy must be established for corrective action when controls are out of the acceptable range.

QC 7 R

Are appropriate reference materials used for controls?

The type of reference materials which should be used for controls should be specified by the manufacturer. The control material which your laboratory uses should be recorded as part of the procedure for each test (or may be included as part of a quality control program for a particular instrument).

QC 8 R

Are the materials used as controls verified by repetitive testing to meet the manufacturer's established parameters for mean and standard deviation?

To verify the mean and standard deviation for a new control lot, the lab should run parallel testing. The new lot of control material should be run as patient samples for at least 5 different days, when possible, along with the current lot of quality control.

QC 9 R

If you use un-assayed controls, do you establish control values by doing concurrent testing with samples of known values?

QC 10 R**Are manufacturer's instructions for the use of reagents, controls, and kits followed?**

This criterion applies to waived and non-waived testing.

Federally waived tests are those that appear on the Food and Drug Administration (FDA) website (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm>). Laboratories must follow manufacturer's instructions for waived tests. CLIA regulations require that waived and non-waived tests be reclassified as non-FDA approved high complexity tests when the laboratory alters or fails to follow the manufacturer's instructions. When this occurs, the laboratory must comply with all high complexity Personnel requirements, and requirements for Performance Specifications for non-FDA approved tests (see VER 5-11).

In addition, waived tests that are modified will be subject to all other requirements for non-waived testing, including, but not limited to Proficiency Testing, Quality Assurance, and Quality Control.

For non-waived tests, laboratories may elect to use reagents other than those of the test system manufacturer. This does not constitute a modification of the test system; however it does require verification of performance specifications (see VER 1-4).

The table below identifies changes which constitute a modification of the FDA approved test system. Examples of modifications include but are not limited to:

Modification of Manufacturer Instructions
Change in specimen handling instructions
Change in incubation times or temperatures
Change in specimen or reagent dilution
Using a different calibration material (or changing the manufacturer's set points)
Introducing a different antibody (source, monoclonal versus polyclonal)
Change or elimination of a procedural step
Change or addition of detector (conjugate) or substrate
Change in solid phase
Change in cutoff or method of calculating the cutoff for semi-quantitative assays
Change in endpoint or calculation of the endpoint Addition of adsorbent
Change in the strain of antigen in serologic assays
Changing the calibrator / reference material
Using a different sample matrix (plasma versus urine)
Using or promoting the test for another purpose (screening versus diagnostic)
Changing the type of analysis (qualitative results reported as quantitative)

QC 11 R

If calibrators and controls are not available for a particular test, are these tests performed according to established methods and are alternative mechanisms used to monitor test performance and detect potential errors?

For tests for which there are no calibrators or control materials available, the laboratory must determine what processes or mechanisms can be used to detect errors that may occur in the complete testing process. Testing procedures should be performed in accordance with standard methodologies whose reliability is supported in literature references. In addition, the laboratory will employ alternative mechanisms such as testing in duplicate, internal or external split samples, comparison of results to other methodologies, correlation of related test results, or other means to detect potential errors. Document all activities performed that are used as alternatives to traditional calibrators and controls.

QC 12 R

Are controls run in the same manner as patient specimens and rotated among all operators who perform the test?

Operator variance can be a significant source of error related to some test methods. For this reason, it is important to make sure that all individuals involved in performing patient testing are involved in performance of quality control as well. Control samples should be handled and tested in the same fashion as a patient to verify that the entire test system is working properly. This process can be used as part of the laboratory's method of verifying competency of employees to perform testing.

QC 13 R

When QC or calibration material is used to establish a cut off value for determining positive or negative reactivity in patient samples, is the test controlled using materials of a different lot number than those used to establish the cut off value?

It is not acceptable to use the same material (lot number) to standardize or calibrate a test system and determine ongoing test accuracy and precision. If there was a problem with the material used to standardize the system, you would not be able to obtain accurate results on patient samples; however you would be unable to detect this through the performance of QC. Essentially a bias would be set in your instrument causing results to be consistently high or low. By using a material of a different lot number you are likely to get something with a different value and different acceptable range. This will allow you to challenge the system and ensure the results obtained are within acceptable limits.

Necessity may require that the same type of material be used as both calibrator and QC for a given test system. When this occurs, the materials used cannot be of the same lot number.

QC 14 R

Do you run controls, before resuming patient testing, when there is a complete change of reagents, major preventative maintenance is performed or any critical part is replaced that may influence test performance?

If you have a complete change of reagents, major preventative maintenance is performed or a critical part is replaced, control materials must be run to verify test performance before patient testing may resume. Refer to your Quality Control program for number and type of controls required for the test system involved.

QC 15 E

If you perform quantitative tests, are two different control concentrations performed each day of patient testing?

QC 16 R

For each quantitative test performed, are quality control data prepared and plotted with each testing event, or are statistical parameters calculated to permit the laboratory to assess continued accuracy and precision of the method?

Control charts, graphs, or statistical parameters (i.e. mean, SD, and CV) should be maintained for all quantitative tests performed by the laboratory. Many instruments and Laboratory Information Systems have the capability to track this information electronically. This data should be reviewed weekly (or following every 5-7 data points if performed infrequently) to detect changes, such as shifts or trends, that may be indicators of test system problems that need to be addressed.

Such routine reviews may permit the laboratory to recognize a developing potential problem and take action to prevent unacceptable results, which could ultimately impact the quality of patient results or create disruptions in access to needed testing due to instrument, test system, or environmental failures.

QC 17 E

If you perform qualitative tests, are positive and negative controls performed each day of patient testing?

QC 18 R

If you perform any direct antigen tests with an extraction phase included, do you check the test system with 2 control materials (including one capable of detecting errors in the extraction process) each day of patient testing?

QC 19 E

If you perform an immunology test which includes titering, is a positive control of known titer or graded reactivity and a negative control run each day a patient test is performed?

QC 20 E

If you use fluorescent and /or immunohistochemical stains, are the stains checked for positive and negative reactivity each time of use?

QC 21 R

Are stains (other than gram or acid-fast stains) checked for positive and negative reactivity (if applicable), and to ensure they provide the expected characteristics on each day of use?

QC 22 E

If you perform a molecular amplification procedure, are two control materials run each day a patient test is performed?

Be aware that if reaction inhibition is a significant source of false negative results, one control must be capable of detecting the inhibition. Check the manufacturer's package insert and supplemental documentation regarding potential sources of error.

QC 23 E

If you run electrophoresis tests, do you perform at least one control concurrent with each patient run, which contains all substances being identified or measured?

QC 24 R

Equivalent Quality Control Option:

As provided for in the past, laboratories may continue to do two levels of external quality control for each day of patient testing. COLA recognizes that CLIA regulations provide an alternative that laboratories may elect for eligible test systems that have successfully completed a qualification procedure. COLA will permit an option to use two of the three Equivalent Quality Control Procedures in place of external QC each day of testing. Laboratories that desire to use these procedures must:

1. Verify the eligibility of their test system,
2. Select the appropriate Equivalent Quality Control Procedure,
3. Successfully complete the qualifying study, and
4. Monitor test and test system performance to include taking corrective action and resuming daily external quality control as indicated in the descriptions below.

Eligibility

To determine if a test system meets COLA's requirements for eligibility to use the Equivalent Quality Control Option, the laboratory must verify that the following requirements are met:

- The test system provides qualitative, semi-quantitative, or quantitative results.
- The test system includes an internal quality control mechanism.
- The test system does not use molecular amplification, thin layer chromatography, or electrophoretic procedures.
- The test system is not subject to specialty or subspecialty quality control requirements included in any of the following sections of COLA criteria.
 - General Microbiology, General Susceptibility, Bacteriology, Mycobacteriology, Mycology, Parasitology, or Virology.
 - Syphilis Serology,
 - Immunohematology

Selecting the Appropriate Equivalent Quality Control Procedure

The Laboratory Director, in consultation with the manufacturer, must explore the potential sources of error within the test system and determine whether the internal control mechanisms are capable of detecting each of the potential sources of error. If the laboratory utilizes a test system that incorporates internal quality control mechanisms that monitor **all or some** potential sources of error, and meets the criteria for eligibility described above, the laboratory director may make the determination to perform equivalent quality control in place of daily external control, in accordance with the protocol outlined below.

Option 1:

If the internal control mechanisms monitor all sources of error, the laboratory must conduct a qualifying study by performing both internal QC and two (2) levels of external QC for ten (10) consecutive testing days. If all results are acceptable for both internal and external QC the laboratory may then perform and document internal QC daily, and perform and document external QC **once per month** unless the manufacturer requires more frequent and/or additional testing of external controls.

Option 2:

If the internal control mechanisms monitor only **some** sources of error, the laboratory must conduct a qualifying study by performing both internal QC and two (2) levels of external QC for thirty (30) consecutive testing days. If all results are acceptable for both internal and external QC the laboratory may then perform and document internal QC daily, and perform and document external QC **once per week** unless the manufacturer requires more frequent and/or additional testing of external controls.

»NOTE: For each option, if any of the following situations occur, the laboratory must stop using the equivalent QC protocol until corrective actions as described below have been completed and documented.

Monitor Test and Test System Performance:

In the event that any of the following situations occur, the laboratory must stop performing the Equivalent Quality Control Procedures and take corrective action.

- Either internal or external QC failures that are not resolved by repeating the control one (1) time.
- PT failure
- Any problems identified with this testing as a result of analytic quality assessment activities.

Corrective Actions to Resume Equivalent Quality Control Procedures:

The laboratory must revert to performing two levels of external QC every day of patient testing during the corrective action period.

- Conduct an investigation to troubleshoot the problem.
- Take corrective action to alleviate the identified or suspected problems.
- Conduct an evaluation of all patients tested since the last acceptable external QC to determine whether patient results may have been affected due to the identified problem. Notify practitioners as necessary.
- Successfully complete another qualifying study prior to resuming Equivalent Quality Control Procedures.

QC 24.1

Has the laboratory determined which equivalent QC protocol will be followed for each eligible test system?

24.2

Did the laboratory successfully complete the appropriate qualifying study?

24.3

Is the laboratory performing and documenting internal and external QC at the appropriate frequency?

24.4

If QC is unacceptable, unsatisfactory PT results were obtained, or QA indicates other problems with the test system, has the laboratory taken appropriate corrective action?

QC 25 R

Are control results reviewed by testing personnel in order to detect possible errors that may occur due to the following conditions:

- **Instrument or procedural failures,**
- **Adverse environmental conditions, AND**
- **Variance in operator performance?**

Testing personnel need to be aware of the importance of ensuring acceptability of results prior to conducting patient testing. A failure in control results can be related to a number of different causes such as reagents, instrumentation, operator error, or environmental conditions. All of which can also impact the accuracy of patient results.

Staff should be trained to routinely review QC results and document acceptability prior to conducting patient testing. Many laboratories elect to have staff initial daily records to indicate that QC was performed and in range. If electronic capabilities exist it is not necessary that computerized reports be printed on a daily basis; however they must at least be reviewed on screen. This should be documented in some fashion. At a minimum the laboratory must be able to demonstrate the QC is reviewed based on corrective action documentation for any unacceptable result.

QC 26 R

Before you begin patient testing, do you take appropriate action and record it when controls exceed acceptable limits?

Daily quality control results must meet your criteria for acceptability prior to reporting patient test results.

QC 27 E

If you run controls at the same time as patient specimens, and you find the controls to be unacceptable, do you re-evaluate patient results that were tested since the last acceptable controls?

Quality Control results must meet your criteria for acceptability prior to reporting patient test results. When QC is performed at the same time as patient testing and the results are unacceptable, the laboratory will need to investigate the reason for the unacceptable QC results, as it may have had an adverse affect on the patient results as well. All results since the last acceptable control run must be re-evaluated. This evaluation could include repeating all patient specimens tested since the last acceptable control depending upon the nature of the system failure.

QC 28 R

Does the laboratory director or qualified designee regularly review the quality control data with laboratory personnel?

The laboratory director is responsible to assure that QC is routinely reviewed to detect and correct potential problems that may impact the accuracy of patient results. This responsibility may be delegated; however the director is responsible for the performance and quality of the review. The QC results which have been reviewed should be initialed by the person reviewing them. The QC review should assess the following for acceptability with laboratory policy:

- Number, type and frequency of QC performance
- Acceptability of QC results
- Corrective action for out of range results.

QC 29 R

Are quality control records retained for at least two years?

QC 30 R

Are all immunohematology quality control records retained for a period of at least ten years?



EVALUATION GROUPING Waived Testing

The addition of this evaluation grouping is a result of COLA's belief that waived testing has the potential to significantly impact patient care. Some of these requirements are not new, but are singled out for emphasis.

NOTE: New requirements include competency assessment for waived testing personnel, and proficiency testing (see WAV 6 and WAV 10).

WAV 1 R

Are manufacturer's instructions followed in the performance of each waived testing procedure and are all kits, reagents, and controls stored according to manufacturer recommendations?

Staff performing laboratory testing need to follow all procedures and manufacturer recommendations as found in procedure manuals, package inserts, and/or instrument manuals. Modifications made by the laboratory to the manufacturer's procedure will be default, change the classification of the laboratory test to high complexity. Any modifications in a procedure must be approved in writing by the laboratory director prior to instituting the change, and the laboratory would then need to abide by all the regulations pertaining to high complexity testing, including personnel requirements and establishment of performance specifications. Refer to COLA criterion QC 10 for examples of what constitutes modification of a procedure.

WAV 2 R

Is all Quality Control performed per manufacturer's instructions, and are the results of QC recorded, reviewed, and found to be acceptable prior to patient result reporting?

*The test system may have both internal and external Quality Control. The results of these controls demonstrate that the test is performing appropriately. These controls must be performed as required by the manufacturer. External QC **must** be performed at the frequency stated by the manufacturer. Prior to reporting patient results, testing personnel must:*

- Perform all required QC,
- Review QC to ensure it is acceptable, and
- Document that QC is acceptable.

WAV 3 R

Do the Quality Control records indicate evidence of corrective action when controls do not give the expected results?

If QC is not acceptable, do not report patient results. Investigate the cause of the QC failure, perform the necessary corrective action, document the action, and re-run control and patient samples. Do not report patient results until the problem is identified and corrected, and QC results are as expected.

WAV 4 R**Are the Quality Control results reviewed monthly by the Laboratory Director or designee?**

On a monthly basis the Laboratory Director or designee must document the review of all Quality Control results to assess

- *That they are being performed and recorded appropriately,*
- *That corrective action has been performed to resolve unacceptable QC results, and*
- *To determine that no patient results were reported when QC was unacceptable.*

If patient results were reported when Quality Control was unacceptable, those patients affected must have medical record reviews to determine if further action is indicated. This review should be documented.

WAV5 R**Are all Quality Control results retained for two years from the date of performance?**

All Quality Control results and results of corrective action should be retained for two years.

WAV 6 R**Is employee competency assessed and documented prior to initiating testing, at six months during the first year of employment, and annually thereafter?**

Each laboratory employee must have competency assessed and documented for each procedure the employee performs. Evaluation of competency should include pre-analytical, analytical and post-analytical phases of testing. This must be done after initial training, six months after initial employment, and annually thereafter. If there is a change in procedure for a given test, or if a new test is introduced into the laboratory, competency assessment must be performed prior to beginning patient testing of the revised or new analyte. All competency results must be retained for two years.

The laboratory must verify that non-laboratory personnel performing waived testing have completed an initial competency assessment prior to testing, a six month evaluation of competency, and annual competency assessments thereafter while they are performing testing. Non-laboratory employees performing only waived testing do not need be listed in the COLA roster of laboratory employees, but the lab is expected to maintain a current, accurate list of all non-laboratory personnel who are performing waived testing.

WAV 7 R**Is a complete, up to date and approved procedure manual readily available to all employees performing waived testing?**

*A procedure manual is not a federal requirement for waived testing; however, federal regulations do require you to follow **all** manufacturers' instructions when performing waived testing. When appropriate, the package insert may be used as the test procedure. If your laboratory is performing several different tests, it is beneficial to create a procedure manual to organize and maintain the various procedures. This procedure manual could be used for all procedures, including those for pre-analytical activities, safety precautions, etc.*

The procedure manual must be signed at least once by the current Laboratory Director. Thereafter, all new and changed procedures must be signed and dated by the Laboratory Director. The manual must be reviewed annually, but this review may be performed by the Lab Director or designee.

When the package insert is used as the procedure, it must be signed and dated by the Laboratory Director prior to initiating patient testing. When new package inserts are received, they should be examined to determine if there have been any changes from prior package inserts. When the package insert is utilized as the procedure, changed package inserts must be reviewed and signed by the Laboratory Director prior to use. If the package insert is not the procedure for the test and the package insert contains changes, appropriate changes must be indicated in the test procedure in use. The changes must be signed and dated by the Laboratory Director.

WAV 8 R**Are there written procedures for pre-analytic activities, such as patient identification, patient preparation, specimen collection and labeling, and accessioning?**

- To produce quality, accurate test results, it is essential to
- Properly identify the patient prior to specimen collection,
- Correctly link the specimen to the patient,
- Process, transport, and store specimens according to manufacturer's instructions.
- Maintain specimen identification throughout all phases of testing.

Developing procedures to address these pre-analytic activities, and ensuring that all personnel follow these procedures will help your lab consistently produce quality test results.

Prior to specimen collection, each patient must be identified by two unique identifiers (e.g., name and birthdate). When possible, specimens should, in turn, be labeled with two identifiers. Specimen collection and handling procedures, included with each procedure, must be followed by all staff performing these steps. If a delay in testing or transport occurs, the specified specimen storage/transport procedures for the test need to be followed.

Specimen collection procedures should also address specimen acceptability criteria. The practitioner should be informed whenever a specimen is unacceptable for the test ordered, so a decision to re-collect the specimen can be made in a timely fashion.

WAV 9 R**Are all patient results appropriately entered into the medical record in a timely manner, and are the results retained for at least two years?**

For every test ordered, a test result needs to be recorded or an explanation provided for the lack of a result. Reports of waived testing results should include the information required in the COLA criteria Post Analytic Section, PST 9-16, 19 and 21. Report critical values to the ordering practitioner immediately, according to your policy. Retain records for at least two years. Longer retention times may be necessary depending on the type of record, and local and state requirements.

The following criterion, WAV 10, is for educational purposes only. If cited during a survey, it will not count against your laboratory.

WAV 10

Is proficiency testing performed for all waived analytes, when available?

Proficiency Testing (PT) is not a federal requirement for waived testing; however, its utilization does represent Good Laboratory Practice. PT serves as an external check to verify the accuracy of your laboratory's test results by providing unknown specimens for you to analyze. It is an important aspect of a laboratory's overall assessment of quality. Laboratories gain significant information about their performance as a result of participation in a Proficiency Testing program. Split specimen testing is another option for verifying the accuracy of your waived tests.

In performance of Proficiency Testing, the following guidelines must be observed:

- a. All Proficiency Testing samples should be examined when they arrive in the laboratory. If the samples are of questionable integrity and replacement samples are needed, the PT provider should be notified immediately. The cut-off date for submission of results should be noted. All Proficiency Testing samples must be treated in the same manner as patient samples. Testing of the PT samples must be assigned randomly to the individuals who routinely perform patient testing. (For further explanation, see annotation for COLA criterion PT 5.)
- b. There **must not be any communication** with any other laboratory regarding PT samples or results **prior to** the cut-off date for the submission of results.
- c. Proficiency Testing samples **must not be sent to any other laboratory EVER**, even if your laboratory is temporarily unable to test them. The PT provider should be promptly notified of any inability to test the PT samples, so your laboratory will not receive an unacceptable score. **Do not send PT samples to another laboratory**, even if your laboratory normally refers patient samples. If your laboratory would normally refer the sample to another laboratory, this should be documented on the result submission form.
- d. All documentation of how the Proficiency Testing samples were handled, prepared, processed, and tested should be retained. Include the booklet provided with the samples by the PT provider, all work sheets, result submission sheets, instrument tapes and logs related to the samples, and the attestation sheet signed by the testing personnel and the Laboratory Director.
- e. When Proficiency Testing results are received, they should be evaluated by the Laboratory Director or a qualified designee. The results of the evaluation should be shared with the testing personnel. All unsatisfactory or unsuccessful PT results should be investigated; consultation obtained, where indicated; and remedial education performed, as appropriate. All results not scored or ungraded should be evaluated. It is recommended that the Laboratory Director review/initial/date **all** Proficiency Testing reports, but at a minimum, should review/initial/date all investigations of unsatisfactory or unsuccessful PT results.
- f. All the Proficiency Testing materials referred to in (e) and (f) above must be retained for two years.

EVALUATION GROUPING:**Specialty-Specific Criteria**

These criteria are part of the Analytic Phase, and apply to the specific specialties performed in your laboratory. This group of questions focuses on testing specialties with specific performance criteria. Those specialties are Hematology, Coagulation (INR), Blood Gases, Urinalysis (refractometer), Microbiology (general, subspecialties, susceptibilities), Immunology/Syphilis serology, and Immunochemistry.

If your laboratory is performing laboratory services for Transfusion Services, then there is an additional criteria section for each of these specialties following the Quality Assessment criteria.

**Guidance on QC Programs for Specialties**

As you establish your quality control program for a specific specialty, you need to consider the number and frequency of controls to perform.

For example:

- If qualitative tests are performed, perform positive and negative controls with each run of patient specimens, or as specified by the specialty requirements
- If quantitative tests are performed, perform two different control concentrations with each patient run, or as specified by the specialty requirements. Refer to your instrument or kit manufacturer's instructions for details on the quality control required for that specific test.

Specialty: Hematology

Most frequently, laboratories performing hematology utilize automated cell counters. You are encouraged to consider your individual operating environment, instrument stability, and personnel competency when determining the total number of times to perform controls each day of patient testing.

You are also encouraged to run all levels of quality control provided for your system each day of testing. This provides a higher level of assurance that results covering the entire reportable range are reliable.

Manual cell counts and blood smear evaluations have their own requirements.

HEMATOLOGY**HE 1 E**

Is all venous blood collected in an anti-coagulant which will not affect cellular morphology or interfere with the cell count?

EDTA (lavender-top tube) is the anti-coagulant of choice. Heparin will distort the cells and should not be used. Note that this question addresses venous collections. Capillary collections do not require anti-coagulant if diluted in saline immediately or may be collected in heparinized tubes, if not being used for the evaluation of cellular morphology.

HE 2 E

Are specimens checked for clots before testing and rejected if clots are detected?

This question applies to instruments that aspirate the specimen, to manual cell counting, and to centrifugal hematology analyzers if the specimen is collected in EDTA prior to processing. It does not apply to centrifugal analyzers in the capillary mode. Check for clots by visually inspecting the specimen while tilting the tube or by stirring the specimen with a wooden applicator stick and looking for clots adhering to the stick.

HE 3 E

If you perform automated hematology, (CBC's and/or reticulocyte counts) are a minimum of two levels of commercial control run each day of patient testing?

Laboratories are encouraged to consider their individual operating environments, instrument stability, and personnel competency when determining the total number of times to perform controls each day of patient testing.

Laboratories are encouraged to run all levels of control provided for their system each day of testing. This provides a higher level of assurance that results covering the entire reportable range are reliable.

Laboratories with multiple shifts may wish to have staff on each shift perform controls. In such cases the laboratory may elect to use a patient control on additional shifts. A patient control is a patient specimen which would have been held over from the morning. It should not be more than twenty four hours old and kept under refrigeration until needed and brought completely to room temperature and well mixed prior to use. The patient specimen should be picked so as to be different from the control to be used. For example, if a normal patient is used, a high or low control should be run or if a normal control is to be used, a patient specimen with abnormal values should be used. The laboratory also needs to establish acceptable ranges for patient replicates. For example, a WBC of +/- 0.5 or an Hct +/- 3.0 of the original value obtained for that specimen may be deemed acceptable. Another option for establishing acceptable ranges is to use the ranges that the control manufacturer has established for the equivalent control to the patient specimen used. For example, use the spread (range) for the high control when using a patient specimen that originally read in the high range as the second control.

HE 4 R

If you perform automated differential counts, have criteria been established for when a manual cell count must be performed to verify the automated count?

You may also answer this question "yes" if you have established criteria for when to send a differential to a reference laboratory. The differential does not need to be performed in-house to meet this criterion.

HE 5 R

If you prepare blood smears, are they properly stained; free of precipitate; and have a uniform cell distribution?

You need to record that your smears are checked regularly for appropriateness of staining. This can be included in the records of your hematology instrument's daily, weekly, or monthly checks.

HE 6 R

Does the blood smear report include an evaluation of red cell morphology?

Red blood cell morphology provides clues to the diagnosis of many diseases, including anemias and sickle cell disease.

HE 7 R

Does the blood smear evaluation include a platelet estimate from the peripheral smear?

HE 8 E

If you perform manual cell counts on a hemocytometer: Is a control counted in duplicate and the results documented at least every eight hours of testing?

Be sure to record the date, time, and result of the control.

HE 9 R

If you perform manual cell counts on a hemocytometer: Are diluting fluids checked to be sure they do not contain contaminants or particles that could falsely elevate cell counts?

If a prepackaged diluting system is used (e.g., Unopette), check at least one vial per lot number to verify an acceptably low particle count. Be sure to record.

HE 10 R

If you perform manual cell counts on a hemocytometer: Are the counting chambers clean and free of scratches?

Dirt and scratches can result in incorrect cell counts.

HE 11 R

If you perform manual cell counts on a hemocytometer: Is a certified or approved coverslip used on the hemocytometer?

The coverslip used on a hemocytometer is precision-ground to fit the chamber. Plain coverslips used in the laboratory do not fit properly and will result in incorrect cell counts.

HE 12 R

If you perform manual cell counts on a hemocytometer: Do you set up manual red and white blood cell and platelet counts in duplicate, count each dilution on one side of the counting chamber, and document the results of each count?

This requirement should be recorded in the procedure manual for these tests. Laboratory records should include the values obtained for each dilution.

HE 13 R

If you perform manual cell counts on a hemocytometer: Are manual platelet counts correlated with a platelet estimate from a peripheral smear?

Be sure to record on a work sheet, if applicable, or on the patient report.



IMPORTANT NOTE

Frequently, ISI values differ from batch to batch or lot to lot of thromboplastin. When values change, the new value must be updated and used in calculating the INR. This is critical for accurate results.

Specialty: Coagulation

There are specific requirements for Coagulation testing and the proper calculation of INR. Manual coagulation tests also have specific requirements.

COAGULATION

The International Normalized Ratio (INR) is rapidly replacing the reporting of “seconds” for Prothrombin times. Correctly calculated INR can allow the clinician to compare patient results from different laboratories more effectively. The use of the INR is becoming the “gold standard” for reporting of Prothrombin time results.

The correct formula for calculating INR is: $(A/B)^C$

A = Patient Prothrombin Time in seconds B = Normal Patient Reference Mean in seconds C = Activity of the Thromboplastin as indicated by the ISI Value assigned by the manufacturer of the Thromboplastin

NOTE: Frequently ISI values differ from batch to batch or lot to lot of Thromboplastin. When values change, the new value must be updated and used in calculating the INR.

When an International Normalized Ratio (INR) is reported: (CO 1-2)

CO 1 E

Does the laboratory have a mechanism to ensure that the correct activity of the thromboplastin, as indicated by the ISI, (corresponding to the current lot number of tissue thromboplastin in use) is used to calculate the INR?

The ISI is the International Sensitivity Index value that is determined by the thromboplastin reagent manufacturer for your particular instrument or method. The ISI is an indication of how sensitive the thromboplastin reagent is in relation to the standard set by the World Health Organization.

NOTE: *Frequently ISI values differ from batch to batch or lot to lot of Thromboplastin. When values change, the new value must be updated and used in calculating the INR.*

Some coagulation instruments calculate the INR automatically, however the user must confirm that the reagent ISI value is updated in the analyzer whenever the lot number of thromboplastin changes.

Some manufacturers will provide a chart to read the INR's off of that are based upon the lot number of thromboplastin in use and its assigned ISI. The laboratory needs to define a process for ensuring the proper ISI is being used in calculations of patient INR's. It is advisable to incorporate this into a routine quality assessment activity, such as part of a chart review process or overall review of coagulation testing.

CO 2 E**Does the laboratory determine the normal patient reference range and mean, with each change in lot number of thromboplastin reagent, and with any change in methodology?**

This range is method, instrument, and reagent specific. The lab must perform a normal patient mean study with every change in lot number of thromboplastin and with any change in methodology, using a sufficient number (minimum = 20) of normal patient specimens. It is not acceptable to use the daily normal control value or the mean of the normal control in place of your normal patient reference mean as the denominator in the INR calculations. You may not borrow a normal patient mean from any other facility.

To minimize the impact of this requirement, many thromboplastin reagent manufacturers will sequester lots of thromboplastin for at least a year at your request. If you have not had a change in your test system in 12 months and don't anticipate a change, it is suggested that you recalculate your normal patient range and mean. This can be done using recent values taken from unmedicated normal patients appropriate for a normal range study.

In those coagulation instruments that calculate the INR automatically, the laboratory must confirm that its normal patient reference range/mean is updated in the analyzer with each new lot of thromboplastin.

NOTE: Frequently ISI values differ from batch to batch or lot to lot of Thromboplastin. When values change, the new value must be updated and used in calculating the INR.

If non-waived AUTOMATED COAGULATION TESTS ARE PERFORMED INCLUDING COAGULATION TESTING ON A FIBROMETER OR SIMILAR SEMI-AUTOMATED INSTRUMENT:**CO 3 E****Are two levels of controls run and documented at least every 8 hours of testing?****CO 4 E****Are two levels of controls run and documented with each change of reagents?**

This includes new reagent which is reconstituted and is the same lot number as the reagent previously used. If manual coagulation tests are performed (CO5- CO7):

CO 5 E**Does each individual perform two levels of control each day before they perform patient tests and document the results?**

Manual coagulation test results may vary greatly among testing personnel. Each person should "control" their own technique. Laboratory records must show who performed the testing.

CO 6 R**Are two levels of controls run and documented each time there is a change of reagents?**

This includes new reagent which is reconstituted and is the same lot number as the reagent previously used.

CO 7 E 3**Are patient specimen and control materials tested in duplicate and the results of each test documented?**

Specialty: Chemistry and Urinalysis

Blood gases, thin layer chromatography, and urinalysis using a refractometer are grouped under Chemistry and have specific requirements as described below.

CHEMISTRY: BLOOD GASES

C 1 E

If your blood gas analyzer doesn't verify itself every 30 minutes, is a calibrator or control run and documented with each patient batch?

C 2 E

Do blood gas analyzers have calibration or calibration verification performed and documented according to manufacturer's specifications with the frequency recommended by the manufacturer?

C 3 E

Is at least one blood gas control run and documented at a minimum every eight hours during each day of testing?

C 4 R

Are a variety of levels of blood gas controls and calibrators (high, low, normal) performed and documented each day of testing?

CHEMISTRY: THIN LAYER CHROMATOGRAPHY

If your laboratory performs thin layer chromatography (questions C5-C7):

C 5 R

Do you spot each plate or card with at least one sample of calibration material which contains all of the drug groups which you report?

C 6 R

Do you run at least one control sample with each plate or card?

C 7 R

Is the control sample used processed through each step of patient testing, including any extractions performed?

URINALYSIS

U1 R

If you use a refractometer to perform urine specific gravity tests, do you rinse the window with water after use?

Dried urine will fog the window and give an inaccurate reading.

U2 R

Are refractometers or hydrometers checked each day of use with distilled water to ensure that a 1.000 reading is obtained?

This routine calibration check assures you that the instruments have not been damaged.

Specialty: MICROBIOLOGY – General, Subspecialties, and Susceptibility

Microbiology is a demanding specialty with requirements for:

- Proper specimen collection
- Media, reagent, disc, stains, and anti-sera quality control
- Proper incubation temperatures and environmental conditions

Subspecialties of Microbiology are:

- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology

There are specific requirements for test performance, organism identification, and quality control for the Microbiology subspecialties.

Susceptibility testing (also called sensitivity testing) has requirements for:

- Use of appropriate control organisms
- Determination of organism susceptibility
- Appropriate control procedures
- Performance of “direct susceptibility” testing

GENERAL MICROBIOLOGY

M 1 R

Are specimens for microbiology cultures collected using the appropriate type of swab or collection device?

Example: Fatty-acids contained in cotton are toxic to N. gonorrhoea, so a non-cotton swab should always be used to collect specimens for GC cultures.

M 2 R

Are specimens plated on appropriate media to support the growth on potential pathogens?

This should be included in your test procedure. Different organisms require the use of special media to supply the nutrients necessary to support their growth or minimize the overgrowth of normal flora.

M 3 R

Is the culture medium at room temperature prior to plating the specimen?

This should be included in your test procedure.

M 4 R

Are cultures incubated using the appropriate incubation conditions for atmosphere and temperature?

Some microorganisms require special atmospheric conditions to enable them to grow. In general microorganisms can be divided into 3 categories based on atmospheric needs: aerobic, microaerophilic, and anaerobic. Aerobic organisms require the presence of oxygen in the atmosphere. These organisms do not require special incubators or procedures to produce an appropriate environment. However, microaerophilic organisms prefer an increased presence of CO₂, while anaerobic organisms require all oxygen to be removed from the atmosphere. Special incubators are available to maintain the required atmospheric conditions to maximize the growth potential. Other procedures such as candle jars or gas packs can be used to create an increased CO₂ or anaerobic environment.

Most microorganisms require an incubation temperature range of 35-39°C. There are several organisms that grow best at alternate temperatures – such as room temp (25°C) or 42°C. The laboratory must know what organisms, the practitioners are seeking from various culture sources and ensure that the laboratory has the capability to provide the appropriate environmental conditions to support growth of these organisms.

M 5 R

Is each batch or shipment of media checked to show:

- **It is sterile; AND**
- **Supports, selects, or inhibits bacterial growth, (as appropriate based on type of media), OR**
- **Has the biochemical reactivity that is expected?**

Documentation available to show that the manufacturer has checked these specifications according to the standards of the Clinical Laboratory Standards Institute can satisfy this requirement.

If your manufacturer has already checked the media in accordance with CLSI standards and states so in the package insert or by letter, the laboratory does not have to repeat these checks. This exception does not include:

- *Chocolate agar,*
- *Campylobacter media, and*
- *Selective media for the isolation of Neisseria species.*

These must be controlled upon receipt in the laboratory due to a high percentage of failure during shipment.

M 6 R**Are media visually inspected before use?**

The general condition of media should be checked upon receipt. Record this check and any action taken in your records. Media should also be checked for the absence of growth prior to inoculation. The absence of growth upon visual inspection of media prior to culture inoculation may also be recorded.

M 7 R**Does the laboratory report any deteriorated or substandard media to the manufacturer?**

If any problems are noted, you should report the problem to your supplier. Record any actions taken in your records.

M 8 R**Where applicable, are positive, negative, and graded reactivity checked with each batch, lot number and shipment of microbiology reagents, discs, stains, and anti-sera when prepared or opened?**

Whether these reagents are prepared in house or purchased commercially, the laboratory must verify proper reactivity prior to or concurrent with patient testing. If performed concurrent with patient testing, and results are not as expected, the patient test may not be reported and must be repeated once the problem has been identified, resolved, and acceptable performance has been verified.

NOTE: For a number of reagents there are ongoing QC requirements further specified in the microbiology subspecialty sections. Please refer to BA 3-5, MYCB 1-2, MYC 1-2, PA 3.

M 9 R**Are positive and negative or graded reactivity checked with each batch, lot number and shipment of identification systems when prepared, received, or when first opened?**

This category includes all biochemical identification systems, either single or combinations of tests for an organism, and systems, such as API strips or Microscan panels. It also includes pre-packaged media combinations such as Uricult or Bullseye, when they are used for presumptive identification of microorganisms.

If these systems are used to report presumptive identification of organisms, the key components, upon which the laboratory's level of identification is based, needs to be validated to give appropriate reactions in the presence of known organisms.

In some cases it may not be feasible to maintain a complete cadre of organisms to be able to establish both positive and negative reactivity for every potential component used by the system to make identification.

The laboratory must challenge the system with the organisms suggested by the manufacturer, commonly available, easily maintained, and that represent those organisms most commonly identified among the laboratory's patient population.



Direct Susceptibility Testing for Urines – Limitations

Some laboratories may elect to perform a modification of the Kirby Bauer susceptibility procedure called direct susceptibility testing. This procedure is only applicable for susceptibility testing of urine. This procedure does allow for faster production of results, but is not widely recognized nor practiced, in part due to the limitations of the method, the additional requirements necessary to validate the test system, and the issues surrounding performance of proficiency testing. A laboratory considering use of this procedure should carefully evaluate the cost and time involved, the typical clinical treatment of its patient population, and the volume of testing.

M 10 R

Does the microbiology record, for each sample, include documentation of the reactivity noted for each step of the identification process?

This documentation will vary based on the identification system in use. It should enable staff to look back and verify that the identification reported based on the reactions observed is valid. Common items to include in documentation are: growth characteristics on various media, positive or negative reactivity with various stain, reagents, or disks. This documentation provides valuable information if there is a question later about the interpretation of results that lead to identification of a specific organism on the final report

NOTES

GENERAL SUSCEPTIBILITY CRITERIA

Laboratories performing bacterial, mycobacterial, or fungal susceptibility testing are required to comply with the general susceptibility questions included in the series below. In addition to these requirements, there are additional subspecialty specific requirements that address the frequency of routine QC.

SU 1 R

Is the laboratory documenting the use of the appropriate organisms/strains for routine quality control testing?

Control organisms for susceptibility testing must be of the proper American Type Culture Collection (ATCC) strain. These represent strains of specific organisms that have defined susceptibility patterns when tested against specific antimicrobial/anti-fungal drugs. Patient isolates may not be used as control organisms. For your assistance, tables are included to describe the most common control organisms used for various type of susceptibility testing. Note that some control organisms are to be performed routinely and others are only necessary when validating new batches, lots, or shipments of reagents

Frequency Of Testing				
Appropriate Control Strain	New lot or batch of media	New lot or batch of antimicrobial agent	Each day if patient isolates are:	Each week if satisfactory 20/30 day study
S. aureus ATCC 25923 (Disc Diffusion method) S. aureus ATCC 29213 (MIC method)	X	X	Gram Positive	X
E. coli ATCC 25922	X	X	Gram Negative (any)	X
P. aeruginosa ATCC 27853	X	X	Gram Negative - non-fermenter	X
E. faecalis ATCC 29212 or 33186	X*			
E. coli ATCC 35218		X**	Gram Negative **	X**

When fastidious organisms are tested, [such as *Haemophilus spp*, *Neisseria gonorrhoeae*, *Streptococcus pneumoniae*], it is necessary to use appropriate media, temperature and environmental conditions in addition to different control organisms to control susceptibility testing procedures. Refer to the CLSI documents, M02-A9 & M100-S17, or the manufacturer's package inserts for guidance.

*Routine use of *E. faecalis* with trimethoprim and sulfonamides is not required if the laboratory has documentation that the manufacturer of the media in use performs quality control for thymine and thymidine levels in the media. Should problems arise with quality control for trimethoprim and sulfonamides, media should be checked with this organism and trimethoprim sulfamethoxazole disks. Satisfactory media should produce:

- a clear distinct zone of inhibition of 20mm or greater (disk susceptibility).
- MIC <0.5/9.5 ug/ml (minimum inhibitory concentration)

** If testing beta-lactam/beta-lactamase inhibitor antimicrobial agents (e.g. ampicillin-sulbactam, amoxicillin-clavulanic acid, piperacillin-tazobactam, or ticarcillin-clavulanic acid) the laboratory should test this organism or an equivalent beta-lactase producing strain.

SU 2 R

Has the laboratory established appropriate minimum inhibitory concentrations or zones diameters for each control organism/agent combination?

It is critical that the laboratory understand that there are two (2) different and distinct ranges of acceptable results involved in susceptibility testing: one for use with control organisms and one for interpreting sensitivity or resistance from patient isolates. The proper range must be used for interpreting results of testing control organisms to verify proper reactivity of reagents and the test system. The interpretive range for sensitivity and resistance will be used for interpreting results of patient testing.

SU 3 R

If you use the Kirby-Bauer method (placing discs on inoculated agar), are no more than 12 sensitivity discs used on 150mm plates or 8 on 100mm plates used?

If you increase the number of disks used the potential for overlapping zones of inhibition increases, which could cause a misinterpretation of the results.

SU 4 R

Do the laboratory records show that each new batch of media and each new lot and shipment of anti-microbial/anti-fungal drugs (disks) are tested prior to or concurrent with initial use, using appropriate control organisms to ensure appropriate reactivity?

The susceptibility test system package insert will define ranges for interpretation of control organisms as well as interpretation of patient isolates. For the purpose of this series of criteria, utilize the table included under SU 1 for control organisms. Appropriate reactivity is met when the laboratory's test result (zone or MIC) for a specific control organism falls within the expected limits defined by the manufacturer, based on the organism and antimicrobial/antifungal drug tested.

Manufacturer's inserts are periodically updated based on data obtained from CLSI - Clinical Laboratory Standards Institute publications on susceptibility testing. It is important to verify the date of publication in use by your laboratory. You will want to have a mechanism to recognize when updated inserts are released that may contain new information or changes in acceptable ranges for interpretation of either control results or patient isolates. This is a wise check to include as part of your quality assessment process.

CLSI documents are useful to laboratories as they provide more detailed discussion of methods and results as well as changes seen from the collection of additional data each year and use of new drugs, etc.... CLSI documents are updated annually and can be obtained directly from CLSI.

SU 5 R

Is the concentration of the control organisms and patient isolates standardized prior to being placed on the media?

SU 6 R

If the laboratory is performing direct susceptibility testing (applicable to Urine Cultures only) are the following parameters established, verified, followed, and documented in the laboratory records?

SU 6.1

Acceptable zone diameters for quality control organisms?

S U 6.2**Interpretive zone diameters for patient isolates?****SU 6.3****Are all quality control organisms tested each day of patient testing?****SU 6.4****Are control organisms and PT challenges tested in the same manner as patient isolates?****SU 6.5****Do laboratory procedures and reports identify the method of testing and its limitations?**

Some laboratories may elect to perform a modification of the Kirby Bauer susceptibility procedure called direct susceptibility testing. This procedure is only applicable for susceptibility testing of urine. This procedure is not widely recognized nor practiced in part due to the limitations of the method, and the additional requirements necessary to validate the test system. This procedure does allow for faster production of results. A laboratory considering using this procedure should carefully evaluate the cost and time involved the typical clinical treatment of its patient population, and the volume of testing.

The procedure calls for susceptibility testing to be set-up directly from the patient urine specimen at the same time that testing is performed to identify the organism present. Since the laboratory does not know what organism will be identified, all QC organisms must be tested each day that patients are tested.

As the concentration of organisms in a patient specimen is not standardized, the laboratory cannot standardize the concentration of control or PT organisms when performing this testing. In addition the laboratory cannot adopt the control or patient interpretive ranges provided in package insert for anti-microbial disks or CLSI documents. The values represented in these documents are only applicable to the use of bacterial suspensions standardized against a 0.5 McFarland standard. The laboratory must design and perform a study to establish its own individual ranges and ensure control organisms and PT samples have randomized concentrations just as a patient specimen would.

SU 7 R**If minimum inhibitory concentrations or zones sizes are not within limits when checked with the appropriate control organism, is corrective action taken and documented prior to reporting patient results?**

If control results are not within acceptable limits this may indicate a problem with the test system which could affect the quality of patient results as well. The laboratory will want to investigate the cause of the unacceptable QC and determine whether any concurrent patient testing may be affected. The laboratory director should establish policy or make the determination regarding when patient testing must be repeated, results held pending results of additional QC testing, or patient results may be reported.

Guidelines for corrective action for daily susceptibility QC:

- *When performing daily testing 1 in 20 results can be expected to be out of range. Any more than this requires corrective action.*

Guidelines for corrective action for weekly susceptibility QC:

- *If there is an obvious reason for the failure such as testing the wrong drug, wrong control organism used, or control contaminated document the reason and retest the strain on the day the error is observed. If acceptable performance obtained, no further action is necessary.*
- *If the reason for the failure is not obvious, test the organism/drug combination for 5 consecutive days beginning the day the error is observed. If all results are acceptable no further action is necessary.*
- *If 1 or more of the 5 results exceeds acceptable limits, the laboratory must investigate further and resume daily QC until the problem is fully resolved. To return to weekly QC, a new 20 or 30 day study is required.*

BA1 R

Are urine cultures performed only on clean-catch, midstream, catheterized, or other appropriately collected urine specimens?

Urine cultures should not be performed on random specimens. Even with a clean-catch, midstream collection, contamination with skin flora is not uncommon. Coagulase negative staph, for example, is becoming a more frequent urinary pathogen, thus making it even more important that a clean catch or other appropriately collected urine specimen be used.

BA 3 R

If you perform beta lactamase testing using methods other than Cefinase, do you use control organisms that provide positive and negative reactivity each day of testing and document the results obtained?

BA 4 R

If you perform Gram stains, do you check for positive and negative reactivity with control organisms each week of use and document the results obtained?

BA 5 R

If you use antisera:

BA 5.1

Do you check the antisera for positive and negative reactivity with control organisms with each new batch, lot number and shipment when prepared or opened and document the results obtained?

BA 5.2

Do you check for positive and negative reactivity with control organisms every 6 months and document the results obtained?

BA 6 R

Is susceptibility quality control performed each day of patient testing, or weekly, if the laboratory has met the requirements to qualify for weekly QC?

The laboratory may elect to perform QC for susceptibility testing on either a daily basis or weekly. The laboratory must successfully complete a qualifying study to decrease the frequency of susceptibility QC from daily to weekly. Refer to BA7 to review the requirements for conducting an acceptable qualifying study.

BA 7 R**Weekly QC option:**

Did the laboratory satisfactorily complete & document results of either a 20 or 30 consecutive testing day study prior to instituting weekly QC?

If the laboratory elects, it may perform QC weekly, as long as the following requirements are met:

20 day: Test each organism with all applicable drugs for 20 consecutive days. Not more than 1 out of 20 zone diameters or MICs, for each organism/drug combination may exceed the expected limits.

30 day: Test each organism with all applicable drugs for 30 consecutive days. Not more than 3 out of 30 zone diameters or MICs, for each organism/drug combination may exceed the expected limits.

AND

Following completion of the study, perform QC weekly in addition to when any components or reagents used in the test system are changed (new batch, lot or shipment).

NOTE: A new study should be conducted whenever any of the following situations occur:

- When a new anti-microbial drug is added to the test panel.
- When the method of reading susceptibility test results is changed (such as from manual to automated).

A new study is also required, following corrective action guidelines that require a return to daily QC to resolve unacceptable performance (a single result exceeding acceptable limits in 5 days of consecutive testing). See SU 7 for discussion of corrective action requirements.

MYCOBACTERIOLOGY SUBSPECIALTY**MYCB 1 R**

If you perform an iron uptake test for mycobacteria, are at least one positive and one negative acid-fast organism checked each day of use and the results documented?

MYCB 2 R

Are all reagents and stains used in mycobacteriology testing procedures checked for reactivity with a positive and negative acid-fast organism each day of use and the results documented?

MYCB 3 E

If you perform anti-mycobacterial susceptibility tests, are all antimicrobial agents checked for appropriate reactivity with a positive control organism each week of use and the results documented?

The laboratory should use a susceptible control strain of Mycobacterium tuberculosis. If automated susceptibility testing is performed, use the control organism and strain recommended by the manufacturer.

MYCOLOGY SUBSPECIALTY**MYC 1 R**

If you use auxanographic media for nitrate assimilation as part of mycological testing, is the nitrate reagent checked with a peptone control each day of use and the results documented?

MYC 2 R

If lactophenol cotton blue is used for mycological identification, is each batch, lot number, and shipment checked for intended reactivity with a control organism when placed in use and are the results documented?

A filamentous fungus, such as Aspergillus, should be used as a control organism.

MYC 3 E

If you perform anti-mycological susceptibility testing, is at least one positive control organism used each day of testing and the results documented?

PARASITOLOGY SUBSPECIALTY**PA 1 R**

If you perform parasite identification, are reference atlases, slides, specimens, and/or charts available for comparison?

PA 2 R

If you use an ocular micrometer for parasite identification, is there documentation to verify that the ocular micrometer is calibrated to ensure accuracy of measurements?

NOTE: *If size is a critical parameter in identifying a parasite, an ocular micrometer must be used. The ocular micrometer should be checked for accuracy on a periodic basis. The manufacturer of the micrometer should provide instructions on how to perform this check. Be sure to record the check.*

PA 3 R

If you use permanent stains for parasite identification, are these stains checked with a fecal control sample containing leukocytes and parasites each month and the results documented?

Be sure to document.

VIROLOGY SUBSPECIALTY**VI 1 E**

If you perform viral identification in your laboratory, do you document the use of uninoculated cells or cell substrate controls cultured simultaneously with patients' specimens as a negative control?

VI 2 R

If you perform viral identifications, do you maintain host systems to cover the full range of isolates necessary to identify the clinical diseases for which you are offering laboratory services?

VI 3 R

If you perform viral testing, are records maintained that describe the systems used and the reactions observed?

Specialty: IMMUNOLOGY/ SYPHILIS SEROLOGY

Syphilis Serology is a commonly performed test in the specialty of Immunology. If your laboratory performs syphilis testing, the following criteria apply.

SYPHILIS SEROLOGY

SY 1 E

Do all the equipment, glassware, reagents, and techniques conform to manufacturer's specifications?

Check for the requirements in the package insert of the kit you are using.

SY 2 R

Are appropriately-sized cards used for testing?

Again, check the package insert for the size circle card which must be used.

SY 3 R

Is the speed of the rotator monitored each day of use?

Check the manufacturer's package insert to determine the speed of rotation required for test performance (this is generally defined as # of rotations/minute). It is important to regulate the speed of the rotator as the rotation has an effect on the antibody/antigen reaction. Too rapid a rate could break up the antibody/antigen reaction, resulting in a false negative. Too slow a rate may inhibit the antibody and antigen from reacting due to lack of adequate contact. This may also result in a false negative result. Be sure to document this check each day of testing.

SY 4 E

Is the needle used for testing calibrated regularly?

Follow the manufacturer's recommendation and record when this is performed. The method for doing this should be included in the procedure for this test.

SY 5 R

Are positive and negative controls being used in the same manner as patient specimens to ensure reactivity and uniform dosages for all test phases?

Specialty: IMMUNOHEMATOLOGY

The general Immunohematology criteria address requirements for blood typing and antibody screens, and the appropriate control procedures for these tests. If your laboratory is involved in the transfusion of blood products in your facility, there are additional “TS” criteria in a separate Immunohematology and Transfusion Services section (following the Quality Assessment criteria) that apply to you.

IMMUNOHEMATOLOGY

IH 1 E

Are typing sera used according to manufacturer’s directions?

IH 2 R

If you perform ABO typing, are patient unknown red cells tested with known Anti-A and Anti-B reagents (forward typing) and are the results of this testing documented?

IH 3 E

If you perform ABO typing, is the patient serum tested with known A1 and B red cells to confirm the forward type (reverse typing) and are the results of this testing documented?

IH 4 E

If you perform Rh (D) testing, are unknown red cells tested with a known Anti-D reagent and are the results of this testing documented?

IH 5 E

Are ABO antisera checked with a positive control each day of use and are the results documented?

IH 6 E

Are Rh antisera checked with positive and negative controls each day of use and are the results documented?

IH 7 E

Is an autologous control used to detect false positive Rh tests and are the results documented?

Check for this requirement in the Rh antisera package insert.

IH 8 E

Are all other antisera in use checked with positive and negative controls each day of use and are the results documented?

IH 9 E

Are ABO reagent red cells checked with a positive control each day of use and are the results documented?

IH 10 E

Are antibody screening cells checked with a positive control containing at least one known antibody each day of use and are the results documented?

IH 11 E

Are anti-human globulin (AHG) reagent (Coombs serum) checked with positive and negative controls each day of use and are the results documented?

Test AHG routinely for IgG only. Anti-complement activity may be checked against complement-coated RBC’s if desired, but is not required. QC for AHG can be performed in one of the following ways: React AHG with a presensitized reagent red blood cell which may be prepared commercially or by the laboratory. Use a known antibody which is demonstrated by the addition of AHG.

Add a presensitized reagent red blood cell to all negative antiglobulin tests to indicate that antiglobulin serum present in the test was not inactivated by unbound globulins or diluted by excess residual saline; therefore, negative results reflect true absence of reactivity. (Using green antiglobulin serum does not substitute for this control.)



IMPORTANT: Maintain Your Records for At Least Two Years

The laboratory needs to retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least two years after the date of reporting. See the Laboratory Document & Record Retention Requirements table located in the criteria.



Record Retention

It is a regulatory requirement that all laboratories ceasing operation make provisions to ensure that all records are maintained and preserved, and available for the specified time frames.

EVALUATION GROUPING: Post-Analytic

The Post-analytic processes follow the analytic phase. The activities covered under this group of questions focus on processes for reporting, distributing, maintaining, and archiving test reports, and for specimen management after completion of testing.

Test Reports

The laboratory must have a system for preparing, releasing, and retaining copies of all reports, including original, preliminary, corrected, and final reports. The final test report should include:

- The patient's unique identification
- Tests performed
- Results
- Reference (normal) ranges for the analytes
- Name and address of the lab performing the test

Additionally, you will want to establish policies for handling and reporting critical values, as well as handling and reporting corrected reports. Include procedures for how the reports are issued, how the affected parties are promptly notified, and the mechanism for maintaining the original and corrected report.

POST-ALYTIC

Refer to procedural requirements in Analytic Section (APM 15, 18, 19)

PST 1 R

Does your laboratory have a written procedure to correct laboratory errors when they are detected?

The laboratory policy should define who to notify when an error occurs, how to correct the error, the importance of maintaining the original and corrected report in case medical decisions or procedures were initiated based on the erroneous result. It should also require that each of these items be documented for review as part of the quality assessment process.

It is important that the laboratory track errors and evaluates the circumstances associated with them, according to their established Incident Management Program, for consideration of potential harm to patients. See Criteria QA 20.

When an error occurs in your laboratory: (PST 2-4)

PST 2 R

Do you have a written procedure to notify the proper individual of the correction?

It is important to notify the person who ordered the test that an error has occurred and, if applicable, any other individual who may be responsible for seeing that appropriate action is taken, in the absence or unavailability of the requester. This should be part of the laboratory's policy manual.

PST 3 R

Do you provide a corrected report to the proper individual?

The corrected report should be labeled as such and provide copies to both the person who ordered the test and if applicable the individual using the test results.

PST 4 R

Do you maintain the original and corrected reports for at least two years, ten years if it is an Immunohematology report, or Pathology or Pap smear report?

This criterion addresses errors in testing performed onsite in addition to testing provided at a reference laboratory (including Pathology, if applicable).

PST 5

R If your laboratory refers tests: Is there a policy that test reports from your reference laboratory may not be altered?

You may not change any reports sent to you by a reference laboratory. If an error was made and you are notified verbally by the reference laboratory, make note of this and make sure you obtain a corrected report from the reference laboratory.

PST 6 R

Does the laboratory policy prohibit reporting test results when they exceed the reportable range established by the laboratory and is corrective action taken and documented in accordance with any deviation in this policy?

Patient results should not be reported in numbers when the results exceed the reportable range. The results may be reported as “greater than” the maximum verified reportable range. An alternative to this would be to follow the manufacturer’s directions for diluting a patient specimen when it exceeds the reportable range. When doing this, however, don’t forget to multiply the result you get by the dilution factor.

PST 7 R

Are test results reported within a reasonable turnaround time?

PST 8 R

Are all test reports sent to the person who ordered the test?

PST 9-16

Does the test report contain:

PST 9 R

The patient’s name and a secondary identifier, to ensure positive identification?

In an effort to ensure positive patient identification and minimize errors related to misidentification, laboratories should use a combination of two identifiers whenever possible on specimens, requisitions and reports.

PST 10 R

The name and address of the laboratory where the test was performed?

PST 11 R

The date(s) the specimen is tested and reported?

PST 12 R

The date of specimen collection?

PST 13 R

The specimen type or source, when appropriate?

PST 14 R

The name of the test performed?

PST 15 R

The test result and its appropriate unit of measure or interpretation, or both?

PST 16 R**The reference range of the test and other pertinent information for interpretation?**

For example, reports should indicate, where applicable for certain therapeutic drug levels, if a sample is a peak level or a trough level.

If you send specimens referred to you to another laboratory: (PST 17-18)**PST 17 R****Is the person who ordered the test aware that the test is being performed at a reference laboratory?**

Be sure to give any practitioner who refers patients to your laboratory a list of tests you perform and keep them informed as to which reference laboratory you use for other tests.

PST 18 R**Are the name and the address of the reference laboratory indicated on the test report?**

If you send the client a copy of the reference laboratory report, it will already contain this information.

PST 19 R**If a specimen is unacceptable, is the condition of the specimen and action taken by the laboratory noted on the testing record and report?****PST 20 R****Is a record kept of who was notified of critical values, as established by the laboratory?**

A record, either paper or electronic, must be kept indicating when an appropriate individual is notified of a critical value. At a minimum the record should include who was notified, when and by whom. As previously noted miscommunication can be a significant source of errors in the health care environment. For this reason laboratories should utilize a read back requirement whenever providing patient results verbally. It is advisable to define this in the procedure for notification as well as including a reminder of the requirement on logs or documents used for notification.

PST 21 R**Are the personnel who performed the test identified on the testing record and test report?**

Each test record and test report should have a space for the person performing the test to initial it.

PST 22 R**Are test records, including instrument printouts that contain patient results, maintained for at least two years?**

All instrument printouts and/or tapes must be retained for two years unless they are directly interfaced with the laboratory information system. Remember that heat sensitive paper printouts tend to fade over time, so you may need to make photocopies of them in order to preserve them for two years.

PST 23 R

Are original or exact duplicate results maintained in a manner that makes them accessible for prompt retrieval?

PST 24 R

Are all original or exact duplicate test reports, either paper or electronic (from in-house tests and reference laboratories), maintained, stored and preserved for at least two years?

The laboratory must have a system for retaining copies of all reports including original, preliminary, corrected and final reports.

PST 25 R

Are all immunohematology original or exact duplicate test reports and test records, either paper or electronic (from in-house or reference laboratories) maintained, stored and preserved for at least ten years?

PST 26 R

Are all pathology, gynecologic cytology, and non-gynecologic cytology reports, either paper or electronic, maintained, stored and preserved for at least 10 years?

This requirement only pertains to laboratories that process Pap and pathology requests and reports through the laboratory. COLA does not accredit testing that falls under the specialty of pathology. Be aware that state regulations may mandate longer retention.

PST 27 R

LABORATORY DOCUMENT & RECORD RETENTION REQUIREMENTS

Document or Record	Minimum Timeframe	Comments
Requisitions	2 years	Patient chart or medical records are acceptable form of requisition provided all required components are present.
Test procedures	2 years beyond date of discontinuance	
QC records	2 years	
Patient test records	2 years	Includes instrument printouts. Patient chart or medical records are acceptable form of report provided all required components are present.
Maintenance and Calibration records	2 years	
Performance Specification Verification records	As long as test system is in use	Not less than 2 years
Blood and Blood product records	See FDA Appendix	Exceptions or modifications shall be made only upon written approval issued by the Director, Center for Biologics Evaluation & Research (CBER).
Immunoematology test records & reports	10 years	
Transfusion records	10 years after records of processing have been completed OR 6 months after the latest expiration date for the individual product - which ever is the later date. If there is no expiration date, the records must be maintained indefinitely.	Records must be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage, and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records must be legible and indelible. They must include the following: <ul style="list-style-type: none"> • Identification of the person performing the work • Dates for all entries • Test results as well as interpretation of results • Expiration dates assigned to specific products
Proficiency Testing records	2 years	
Quality System Assessment	2 years	Previously called Quality Assurance
Test Reports – (preliminary, final, and corrected)	2 years beyond the date of reporting	
Pathology & Cytology test reports	10 years beyond the date of reporting	



QA: Systematic Approach to Quality and Safety

The purpose of the QA review is to monitor whether processes and procedures related to general, pre-analytic, analytic, and post-analytic phases of laboratory testing are being performed properly. The intent of the program is to utilize a systematic approach to monitoring, assessing, and correcting problems identified in laboratory processes on an ongoing basis.

EVALUATION GROUPING: Quality Assessment (QA)

In addition to external quality assessments such as proficiency testing and the COLA accreditation process, it is important for your laboratory to implement an internal Quality Assessment (QA) program. Internal assessments represent those activities conducted by staff to audit compliance with the laboratory's policies, processes, and procedures, and to identify opportunities for improvement. A quality assessment program also helps standardize testing in the laboratory, identifies sources of error in patient testing, and includes regular monitoring and evaluation of all aspects of the laboratory's activity, from specimen collection to the delivery of the report to the physician. Quality Assessment is designed to ensure reliability and medical usefulness of the laboratory results.

Quality Assessments – Focus and Frequency

Assessments or reviews should be performed on an ongoing basis and should evaluate the general, pre-analytic, analytic, and post-analytic phase of laboratory processes throughout the year. COLA suggests that you consider what activities, if not performed properly, have the most significant impact on the quality of testing or the level of service provided by your laboratory.

To evaluate the level of service you provide, select a minimum of one monitor for each phase noted above. "Monitors" are things you look at to evaluate the quality, effectiveness, and efficiency of a process or activity. Use these monitors to conduct assessments throughout the year to evaluate performance, design process improvements, and track the effect of their implementation.

As the assessments reveal deviations between policy and performance, this alerts the laboratory that a problem exists. The laboratory must then review the process and data obtained by the assessment to develop corrective actions aimed at resolving problems and preventing recurrence. It is important to share findings of quality assessment activities with your staff, and to conduct follow-up reviews to determine the effectiveness of corrective actions.

Incident Management

The laboratory must establish policies and procedures and document their use in managing incidents, particularly those that caused or may potentially cause death or serious injury to patients or laboratory staff. An incident management plan (IMP) provides the structure for these activities. The goal is to identify, learn from, and prevent such incidents from occurring.

An incident is defined as an event that results in, or has the potential to result in, death, or serious injury for patients or laboratory staff. For example, an improperly labeled specimen could have serious consequences.

Incidents may be first identified as part of a QA review conducted by the laboratory. This is not to say that every issue identified in a QA review requires an incident report. The QA review may reveal instances of noncompliance with laboratory policies that if left uncorrected could lead to an incident. The intent of these criteria is to focus attention on the most serious consequences and outcomes that may occur as a result of laboratory activities associated with patient diagnosis, care, and treatment.

QUALITY ASSESSMENT

QA 1 E

Have you established a written Quality Assessment Program comprised of policies and procedures for ongoing mechanisms to monitor, assess, and correct problems in general, pre analytic, analytic, and post analytic processes?

A written Quality Assessment Program incorporates all the processes in the laboratory (general, pre-analytic, analytic, and post analytic). The intent of the program is to utilize a systematic approach to monitoring, assessing, and correcting problems identified in laboratory processes on an ongoing basis. A complete program includes establishment of communication mechanisms for staff, documentation of all activities, and follow-up reviews to determine the effectiveness of corrective actions. The program should also include planned reviews for the year. A schedule or calendar should be established, specifying when system reviews are to be performed.

QA 2 E

Has the laboratory implemented its Quality Assessment Plan and performed ongoing reviews of all processes and procedures?

Quality Assessment reviews performed throughout the year should evaluate the general, pre-analytic, analytic, and post-analytic phases of laboratory processes. COLA suggests that laboratory personnel prioritize those activities which have significant impact on the quality of testing or the level of service provided if not performed properly. Ensure that these activities are monitored according to your Quality Assessment Plan. Conduct Quality Assessment reviews of each process throughout the year according to your Quality Assessment Plan. Evaluate results of the reviews, design process improvements, take corrective action as needed, notify all staff of any changes, and monitor the effect of implementation of actions taken.

QA 3 R

Do your Quality Assessment reviews enable the laboratory to identify and correct problems?

The purpose of the Quality Assessment review is to monitor whether processes and procedures related to pre-analytic, analytic, and post-analytic phases of laboratory testing are being performed properly. As the assessments reveal deviations between policy and performance this alerts the laboratory that a problem exists. The laboratory must then review the process and data obtained by the assessment to develop corrective actions aimed at preventing recurrence.

QA 4 R

Does your Quality Assessment Program include a process to conduct follow-up reviews to assess the effectiveness of corrective actions?

The Quality Assessment Program can only be effective if it permits timely identification and correction of problems and implementation of solutions to prevent reoccurrences. A follow-up review and analysis insures that corrective actions have corrected the problem identified

QA 5 R

Is the information obtained during a quality assessment review shared with the laboratory staff and other individuals as appropriate and is this recorded?

The director or consultant should discuss the quality assessment review with all appropriate staff so that everyone knows what problems were identified and what corrective actions are being implemented. By involving staff in the review and correction, one can better assure that the root cause of the problem will be identified and corrected.

Effective communication of Quality Assessment issues is essential in preventing recurrences. Documentation of these activities is essential to create a record that can be referred to in the future, should questions arise.

PRE-ANALYTIC ASSESSMENTS**QA 6 R**

Does the quality assessment review evaluate the laboratory's processes for patient preparation, and for specimen collection, handling, labeling, transport, and acceptability?

The review should look at these criteria and determine if they are correct and appropriate for your lab, and verify that lab personnel are following them.

QA 7 R

Are quality assessment reviews performed to assess requisitions for completeness and relevance of content, including inconsistencies of age, gender, and, when available, diagnosis or pertinent clinical data, and relationship with the requests and/or results of other tests?

Many laboratories utilize a chart audit or medical record review to easily assess the Patient Test Management System. In the Pre-analytic phase this review should concentrate on the process for ordering tests, including assessment of the completeness and relevance of content of test requisitions, as well as retention of requisitions.

QA 8 R

Are all communication breakdowns between physicians (or other persons authorized to order tests) and laboratory personnel recorded and are corrective actions documented?

This is generally not a problem in a small office lab. It can be a major problem if your laboratory accepts referral specimens.

ANALYTIC ASSESSMENTS**QA 9 R**

Does the quality assessment review evaluate the corrective actions taken by laboratory personnel when quality control or calibration is out of range or instruments are out of calibration?

The QA review should look at several months of QC, calibration and maintenance records to see if the laboratory staff is identifying and taking corrective action when problems occur. Beyond this, the laboratory should look for patterns among the incidents requiring corrective action and the actual actions taken. Identification of a pattern of repetitive events is a trigger that something in the process is going awry. Identification of the root of this issue and formulation of process changes to prevent future occurrences is the goal of the QA program.

QA 10 R

Does the quality assessment review evaluate situations that indicate instruments or kits may no longer be meeting stated performance specifications and the corrective actions taken in response to such situations?

Performance specifications for:

- 1) *Unmodified FDA-cleared or approved test systems include accuracy, precision, reportable range of test results, and verifying manufacturer's reference ranges (normal values) are appropriate for the laboratory's patient population.*
- 2) *Modified FDA-cleared or approved test systems or a test system not subject to FDA clearance or approval (methods developed in house) requires accuracy, precision, sensitivity, specificity, reportable range of test results, reference intervals (normal values), and any other performance characteristic required for test performance.*

As part of the QA process, you want to ensure that performance specifications have been completed and assess whether information from the review of other activities (such as discrepancies in the relationship or distribution of other test results, incorrect reference ranges, or patterns related to repetitive corrective actions for QC and calibration issues) indicates a change in the test system and its expected performance specifications that requires further investigation and corrective action.

QA 11 R

Does the laboratory have a process or mechanism in place to evaluate and adjust the reference range when it is determined that the reference range has changed?

A review of your patient population relative to the use of a generally established reference range may reveal the need to establish your own reference range because of the uniqueness of your patient population (e.g., geriatric patients, altitude).

QA 12 R

If you perform the same test using different methods or instruments, do you evaluate the variance in the results produced by each method at least twice a year?

When multiple methods are used to perform the same test, it is important for the laboratory and the practitioners it supports to understand the relationship between results produced by each method. This is most critical when tracking results on a specific individual over time. If significant variances in results are present, they could potentially be interpreted as denoting changes in the patient's condition, when in fact they are merely the result of a bias among methods.

This is easily done by split specimen analysis. If any bias is noted, it is important to reflect the difference in the reference ranges that are used on the test report. This requirement also includes back-up instruments.

QA 13 R

When your PT results are unsatisfactory, do you take action to prevent future failures?

Neglecting even a single failure in PT can cause the laboratory major problems. The QA review of PT should include a review of QC and calibration records, transcription errors in recording the PT result, expiration dates on reagents, etc.

QA 14 R

Does the laboratory have a process or mechanism to detect and review patient test results that appear to be inconsistent with the distribution of patient results, the relationship with other test results or any information relevant and necessary to interpretation of patient results?

POST-ANALYTIC ASSESSMENT

QA 15 R

Does the quality assessment review assess test reports for completeness and relevance of the content, distribution of results to the appropriate parties, and maintenance of original or exact duplicate reports for the required time periods?

Many laboratories utilize a chart audit or medical record review to easily assess the post-analytic portion of the Patient Test Management System. In the Post-analytic phase, this review should concentrate on the processes for reporting, distributing, and maintaining test reports.

In this phase, you will also want to evaluate compliance with policy for handling and reporting panic values as well as handling errors. When assessing errors focus on how the error was identified, what permitted the erroneous report to be released, and whether corrected reports were issued, affected parties promptly notified, and records kept of the original and corrected report.

QA 16 R

Are test turnaround times (such as STATs) evaluated to ensure results are obtained in a clinically useful period?

GENERAL ASSESSMENTS

QA 17 R

In order to ensure the validity and effectiveness of the process provided by the Laboratory Information System (LIS) monitor all elements related to pre-analytic, analytic, and post-analytic processes. The LIS is an electronic based laboratory data system.

Does the quality assessment review of the Laboratory Information System include:

QA 17.1

Accuracy and precision of the data entry process, whether manual or automated?

A review of the accuracy and precision of the data entry process, (manual or automated) may be conducted by comparing test records (tapes or screen values) to the data contained in the computer and printed on the report. The patient information, entered through barcode or requisition information, should also be validated for accuracy.

QA 17.2

Correctness of computer calculations performed on patient data?

QA 17.3

Evaluation of data storage and recovery?

Data storage and recovery systems should be assessed regularly to assure data is not lost, but can be appropriately stored and can be retrieved in a timely manner.

QA 18 R**When there are complaints about the laboratory, is the complaint evaluated and, if necessary, is corrective action taken?**

The laboratory should have a protocol for dealing with complaints. Every complaint should be taken seriously and should be investigated by the laboratory director or supervisor. If the complaint is justified, corrective actions should be taken to remedy the problem. The QA review should look at these complaints to determine if there is a generalized problem in the lab, to be sure that the protocol is followed, and that appropriate action has been taken.

QA 19 R**Are records kept of complaints about the laboratory and the corrective actions taken concerning these complaints?**

As with all laboratory activities, documentation is necessary.

QA 20 E**20.1****Has the laboratory developed and implemented written policy and procedures to identify, evaluate, manage, and correct any incidents, resulting from Non-compliance with stated policies and procedures?****20.2****Does the laboratory have procedures for the identification, evaluation, management, and correction of any unexpected event which has caused, or has the potential to cause, death or serious injury to patients or laboratory staff?**

The laboratory must establish policies and procedures and document their use in managing incidents, particularly those that caused or may potentially cause death or serious injury to patients or laboratory staff. The goal is to identify, learn from, and prevent such incidents from occurring.

Incidents may be first identified as part of a QA review conducted by the laboratory. This is not to say that every issue identified in a QA review requires an incident report. The QA review may reveal information about Non-compliances with laboratory policies that if left uncorrected could lead to an incident. The intent of this criterion is to focus attention on the most serious consequences and outcomes that may occur as a result of laboratory activities associated with patient diagnosis, care, and treatment.

A series of examples of laboratory incidents are listed below:

- laboratory errors (incorrect test results reported leading to misdiagnosis or improper treatment OR wrong test performed on wrong patient delaying diagnosis or treatment)*
- accident/injury (reagent spill causes staff member to fall, improper disposal of waste materials causes injury to staff or patients, employee needle stick as result of phlebotomy)*
- complaint (patient complains of excessive pain, burning, numbness or tingling during/after phlebotomy that may indicate injury from the phlebotomy procedure)*
- recognized systemic non-compliance with stated policies and procedures of the laboratory that has a significant negative impact on the accuracy and reliability of test results ultimately affecting patient outcomes or staff safety.*

QA 21 R

Are all Quality Assessment activities documented?

Quality Assessment documentation should be comprehensive and include the following:

- *The activity being monitored,*
- *Data collected during the assessment,*
- *The results of the assessment (problems identified or not),*
- *Corrective action for any problems identified.*
- *The time frame covered by the assessment,*
- *Date assessment performed, and*
- *Initials of those involved.*

The final step is documentation of the follow-up review. The follow-up review should be documented in the same manner as the initial review, to facilitate comparison of results. COLA LabGuide 70—“Quality Assessment in the Office Laboratory” has a sample QA form which you can copy for your own use.

QA 22 R

Are all quality assessment records retained for two (2) years and maintained in a manner that makes them easily retrievable for review?

All quality assessment activities should be documented and available for review by the director, consultants, and surveyors.

Immunoematology and Transfusion Services

In addition to the general Criteria and Self-Assessment questions, there is a separate set of Criteria and Self-Assessment questions that only applies if your laboratory performs compatibility testing, antibody identification, OR if your facility transfuses blood products to patients.

This set of criteria is divided with section headings that indicate the aspect of laboratory operation being addressed. For example, the Immunoematology and Transfusion Services questions have sections for:

- Management
- Storage, Transportation, and Dating
- Quality Control
- Recipient Testing for Transfusion
- Computerized Systems
- Recipients with Special Needs
- Dispensing Requirements
- Units for Reissue
- Transfusion Reactions
- Record Keeping and Documentation

IMMUNOHEMATOLOGY AND TRANSFUSION SERVICES

Introduction

The following standards and criteria are applicable to any facility involved in the provision of transfusion services. This includes facilities that do not perform testing within the specialty of Immunohematology, but administer blood products to patients.

Facilities requiring FDA Registration:

- Those that engage in the manufacture of blood products, to include the collection, component preparation, product testing, labeling, storage, and distribution of blood products.
- Those that manipulate blood products including irradiation, freezing, deglycerolizing, and washing cells.

Facilities that are approved for Medicare reimbursement may be exempt from FDA Registration if their services are limited to the following items. (CFR 607.65 f):

- Engage in compatibility testing and transfusion of blood products, but neither routinely collect nor process blood and blood components.
- Those that may collect and process blood and blood components only in an emergency situation as determined by a responsible person and documented in writing.
- Those that perform therapeutic collection of blood or plasma that is not intended for transfusion.
- Those that solely prepare Red Blood Cells or Recovered Plasma, pool Platelets or Cytoprecipitated AHF for ease of transfusion, or issue bedside leukocyte reduction filters.

NOTE: *The blood products described above, must be intended for use within the facility. If the facility were to send the product to another facility, FDA registration is required.*

For additional information contact the Center for Biologics Evaluation and Research at the FDA. (By phone 301-827-3546 or email bloodregis@cber.fda.gov)

There are several types of facilities involved in the provision of transfusion services.

Blood Banks: A facility that collects and/or processes blood products in preparation for transfusion. Such facilities may also distribute blood products to outside facilities, perform immunohematology testing and administer blood products to patients.

Transfusion Services: A facility that is not involved in the collection or processing of blood products, but is involved in the administration of blood products to patients.

COLA further divides Transfusion Services into two categories.

1. **Full Transfusion Service:** A facility performs immunohematology testing and administration of blood products.
2. **Blood Storage & Administration:** A facility that does not perform immunohematology testing on site, but receives and administers blood products. For these facilities not all criteria contained in this document will be applicable considering the limited level of service.

COLA Accreditation includes an evaluation of laboratory policies, processes, and records associated with the following:

- Laboratory testing performed on potential blood donors (such as hemoglobin and hematocrit)
- Laboratory testing performed on blood components (such as ABO& Rh, HIV, hepatitis, etc...)
- Laboratory testing of blood products for compatibility with an intended recipient (such as ABO & Rh, Antibody screening, compatibility, etc)
- Storage of blood products
- Dispensing blood products for intended transfusion
- Basic requirements associated with administration of the product to the intended recipient
- Investigation of suspected transfusion reactions and associated laboratory testing (such as ABO & Rh, DAT, haptoglobin, etc...).

COLA Accreditation does not include evaluation of policies, processes, and procedures associated with donor suitability, collection of the blood product, manufacturing (processing) the blood product, and recall of blood products or donors.

Management

TS 1 E

Is your transfusion service properly registered with the FDA if it is not exempt from FDA registration according to 21 CFR 607.65 (f)?

Facilities that draw donors and process donor units must be registered with the FDA. Laboratories processing donor units beyond:

- *The packing or aliquoting of RBC's,*
- *Issuing of bedside leukocyte reduction filters, • Thawing FFP,*
- *Pooling Platelets of Cyroprecipitated AHF are not exempt from these regulations.*

TS 2 R

Do you have a written agreement between your facility and other facilities governing the availability, procurement, testing and transfer of blood and blood components that are provided to you by those facilities, and does the agreement meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients who are served by your facility?

Does the laboratory director:

TS 3 E

Provide facilities adequate for procurement, safekeeping, and transfusion of blood and blood components as specified at 21 CFR 606.40?

TS 4 E

Ensure that procedures are in place for the storage, testing, dispensing and transfusion of blood and blood components?

TS 5 E**Ensure that all delegated responsibilities are properly performed?**

Laboratories should be aware that the following tests, on both donor and recipient testing, are considered high complexity when performed for the purpose of compatibility and transfusion of blood products.

- ABO and Rh Type
- Antibody Screen
- Compatibility
- Direct Antiglobulin Test (DAT)
- Unexpected Antibody Identification
- Antigen typing

As such the laboratory must ensure that a qualified General and Technical Supervisor is identified to oversee the transfusion service. The functions of a transfusion service are unique in comparison to other specialties within the laboratory. Frequently the individual(s) that fulfill the duties of General and Technical Supervisor for other specialties of the laboratory do not have the education, training and experience to perform these functions for the transfusion service. For this reason, many laboratories will need to designate different individuals to fill the role of General and Technical Supervisor for the Transfusion Service. These individuals must meet requirements for education and experience as defined in the Personnel Requirements chart in Section III. This section also details the responsibilities of the individual holding each position.

As part of the laboratory's personnel competency assessment program, the education, training, and performance of duties and responsibilities of the General and Technical Supervisor should be assessed to assure quality of laboratory service and promotion of patient safety.

TS 6 E**Provide adequate consulting services or obtain outside expertise when needed for special problems? Storage, Transportation and Dating?****TS 7 R****Are readily accessible written procedures in effect that detail proper storage temperatures and how they are to be monitored and controlled?****TS 8 E****Do the laboratory records demonstrate that units used for the storage of blood and blood components assure adequate maintenance of the temperatures desired?****TS 9 R****Are temperatures of areas used for the storage of blood and blood components, i.e. refrigeration units, freezers, ambient air; continuously recorded or manually recorded every four hours?**

If a recorder is used (TS 10 - TS 12):

TS 10 E**Is it checked against a thermometer daily?**

TS 11 R

Are the recorder charts changed when needed?

TS 12 R

Are the recorder charts initialed, dated and retained?

TS 13 R

Does an audible alarm sound indicating a power failure or other disruption of refrigeration?

TS 14 R

Are written procedures in place permitting immediate corrective action to occur 24 hours a day in response to an audible alarm?

TS 15 R

Are alarm checks performed and documented that verify the temperature at which the audible refrigeration alarm will sound?

TS 16 R

Are explanations for temperature deviations documented?

TS 17 E

Are all blood and blood components stored and shipped at the required temperatures according to applicable FDA guidelines at 21 CFR 610?

Guidelines specify:

- **Whole blood and red blood cell components and liquid plasma** — stored between 1-6 degrees C and shipped at 1-10 degrees C. Frozen RBC's — stored at minus 65 degrees C.
- **Fresh frozen plasma(FFP)** — stored and shipped at -18 degrees C. If needed for coagulation factors, should transfuse within 24 hours.. Thaw at 30-37 degrees C. and kept at 1-6 degrees C. in the interim prior to transfusion.
- **Cryoprecipitated Antihemophilic Factor Human (AFH)** — stored and shipped at -18 degrees C. If needed for factor VIII, should transfuse within 6 hours. Thaw at 30-37 degrees C. and held at room temperature in the interim.
- **Platelets and Platelet-rich plasma** — stored and shipped at 20-24 degrees C. or 1-6 degrees C. Blood or plasma should be held at 20-24 degrees C. prior to separation of platelets that should be done within 4 hours of collection. Once separated, they should be continuously maintained at either 1-6 degrees C. or 20-24 degrees C. If stored at 20-24 degrees C., a continuous gentle agitation (or rocking) must be maintained throughout the storage period. Agitation is optional at 1-6 degrees C.

TS 18 R

Are special areas defined for the storage of blood and blood components that avoid contamination or exposure to hazardous materials?

TS 19 R

Are areas clearly designated for the storage of available, crossmatched, quarantined, autologous and directed units?

TS 20 R

Is the maintenance of the proper storage temperatures of blood or blood components assured when units are held outside of the laboratory's control (E.g. ICU, ER, or OR)?

This requires a method of assuring that once units are released for transfusion they are used promptly or stored appropriately, then returned to the lab in a timely fashion thus suitable for reissue.

TS 21 R

Do the containers used for the transport of blood and blood components assure maintenance of the desired temperatures during shipping?

Record periodic checks performed to verify their capacity to maintain required temperatures.

TS 22 R

Are all blood and blood components promptly disposed of after the product's expiration date has passed and retention for further testing is not required and is there a record of disposal?

TS 23 R

Is there documentation of the visual inspection of units of blood and blood components prior to shipment or release for transfusion?

Quality Control**TS 24 E**

Are ABO antisera checked with a positive control each day of use and are the results documented?

An easy way to do QC on ABO reagent red cells (antigens) and ABO reagent antisera (antibodies) is to use each to QC the other. By reacting A cells with anti-A and anti-B and B cells with anti-A and anti-B, you have successfully cross-check each reagent.

TS 25 E

Are Rh antisera checked with positive and negative controls each day of use and are the results documented?

TS 26 E

If the laboratory uses a protein based Rh antisera, is a special protein based control reagent, similar to the formulation of the Rh antisera in use, performed to detect possible false positive Rh tests and are the results of this testing documented?

There are different types of Rh Antisera. The most common reagents presently in use are saline based, monoclonal antisera. These products do not require the use of a separate control to detect false positive Rh tests.

Laboratories still using a protein based antisera, should consult the manufacturer's instructions for selection of a protein based reagent that matches the formulation of the Rh antisera in use. The laboratory will incubate patient cells with the protein based reagent to detect spontaneous agglutination that may contribute to a false positive result. The patient's Rh test and the control procedure described above must be performed simultaneously.

TS 27 E

Are all other antisera in use checked with positive and negative controls each day of use and are the results documented?

TS 28 E

Is ABO reagent red cells checked with a positive control each day of use and are the results documented?

An easy way to do QC on ABO reagent red cells (antigens) and ABO reagent antisera (antibodies) is to use each to QC the other. By reacting A cells with anti-A and anti-B and B cells with anti-A and anti-B, you have successfully cross-check each reagent.

TS 29 E

Are antibody screening cells checked with a positive control containing at least one known antibody each day of use and are the results documented?

TS 30 E

Are anti-human globulin (AHG) reagents (Coombs serum) checked with positive and negative controls each day of use and are the results documented?

Test AHG routinely for IgG only. Anti-complement activity may be checked against complement-coated RBC's if desired, but is not required. QC for AHG can be performed in one of the following ways:

- *React AHG with a presensitized reagent red blood cell which may be prepared commercially or by the laboratory.*
- *Use a known antibody which is demonstrated by the addition of AHG.*
- *Add a presensitized reagent red blood cell to all negative antiglobulin tests to indicate that antiglobulin serum*
- *Present in the test was not inactivated by unbound globulins or diluted by excess residual saline; therefore, negative results reflect true absence of reactivity. (Using green antiglobulin serum does not substitute for this control.)*

Recipient Testing for Transfusion

TS 31 R For Allogenic Transfusions:

Are pre-transfusion immunohematology specimens for testing of recipient's blood obtained within 3 days of the anticipated transfusion if the patient's history is not known or there is evidence of pregnancy or transfusion within the last 3 months in accordance with laboratory policies?

NOTE: The specimens used for this testing must accurately represent the patient's serologic status at the time of transfusion. If there is no evidence of recent immunologic stimulus, i.e. transfusion or pregnancy, the time frame between specimen collection and transfusion is not critical. The laboratory must document and retain verification in the patient's history records that the transfusion and pregnancy history were verified. The laboratory must have a policy defining acceptable specimen collection dates for transfusion based on the patient's transfusion and/or pregnancy history.

Time limits do not necessarily apply to patients receiving autologous transfusions unless they have a history of transfusion or pregnancy in the past 3 months or allogenic transfusions are begun after the first specimen is obtained.

The day the recipient's specimen is obtained is day 0. The transfusion should be administered prior to the conclusion of day 3 and/or per established time limits for specimen use if there have been no transfusions and/or pregnancies in the prior three months. If the recipient's transfusion or pregnancy history is unknown or the recipient has received one or more units since the initial specimen was drawn, a new specimen must be obtained at the conclusion of day 3.

Are blood specimens for immunohematology testing (TS 32 – TS 36):

TS 32 R

Obtained using tubes with firmly attached labels?

TS 33 E

Labeled with a unique patient identifier composed of 2 individual identifiers?

To contribute to the reduction of medical errors as a result of mis-identification, it is necessary for laboratories to ensure that all specimens have a unique identification that can be linked to the patient, requisition, and report. Using a combination of two identifiers, increases the likelihood of catching misidentifications due to common names.

Examples of common identifiers include birth date, medical record number, or social security number. Birth date is acceptable but it may be possible to have two patients with the same or similar name and the same birth date. The room number is never acceptable.

TS 34 E

Labeled with the patient's first and last names?

TS 35 E

Labeled with the date drawn?

TS 36 E**Drawn and then labeled while still at the patient's side?****TS 37 R****Is there a mechanism to easily identify the individual who drew the specimen?**

It is critical to be able to confirm the identity of the individual that collected the specimen. This can be accomplished in a number of ways. Historically phlebotomists have signed their name or recorded their initials directly on the specimen label. This is not a requirement, as long as the facility can trace the identity of the phlebotomist by another means. This is most common in facilities that are computerized.

Are final interpretations of test results immediately documented as testing of blood specimens obtained from potential transfusion recipients is completed for the following tests (TS 38 – TS 40):

TS 38 E**ABO group and Rh type?**

Tests for weak D are not required.

TS 39 E**Unexpected antibody screen that will demonstrate clinically significant red blood cell antibodies reactive at 37 degrees C?****TS 40 E****Antibody identification, if antibody screen was positive?****Compatibility Testing****TS 41 R**

Prior to compatibility testing, are all units of whole blood and red blood cell components retyped to confirm ABO group and Rh D negative labeling from an attached segment?

Some transfusion services perform retypes as units are received from the blood supplier and some do them as the crossmatch is being performed. Either is acceptable as long as it is documented. Tests to confirm Rh positive labeling or tests to confirm for weak D are not required.

TS 42 E**Are recipient's historical records reviewed and documented prior to selecting units for transfusion?****TS 43 R**

Does the procedure manual include criteria for selecting appropriate ABO and Rh types of red blood cells and components for patient transfusion?

TS 44 E**Are all donor cells cross-matched with recipient serum or plasma prior to transfusion?**

Immediate spin crossmatch only detects ABO incompatibility and is adequate only if both donor and recipient test negative for clinically significant red cell antibodies and there is no record of previously detected red cell antibodies. It is also adequate in life-threatening emergencies, or for autologous or neonatal transfusions.

If a crossmatch is performed at another facility and the unexpected antibody screen was negative, the administering facility need only confirm ABO compatibility.

TS 45 E**Are an antigen screen of the donor unit and a major crossmatch performed prior to release of a unit for transfusion when the antibody screen of the recipient was positive, either currently or historically, for clinically significant red cell antibodies?****Computerized Systems****TS 46 E****If a computerized compatibility testing and record keeping system is in use has the system been validated onsite according to accepted protocol?**

Your system should:

- *Be used only when ABO compatibility testing is required.*
- *Be used only if there are two separate determinations of a recipient's ABO group.*
- *Contain donor unit number.*
- *Contain component type/name, e.g. frozen red cells.*
- *Contain ABO group of donor.*
- *Contain Rh type of donor.*
- *Contain interpretation of ABO confirmatory test.*
- *Contain recipient identification.*
- *Contain recipient ABO group and Rh type.*
- *Have a method to verify correct entry of all of the above data.*
- *Have system logic to alert for discrepancies between donor/recipient information and potential incompatibility.*
- *Incorporate a level of security needed to protect the validity of information.*
- *Have a plan of recovery after failure.*
- *Have manual backup procedures.*
- *Maintain backup records.*
- *Have complete instructions for system start-up and shut-down.*

Recipients With Special Needs

TS 47 E

Has protocol been established that specifies the types of units and level of compatibility testing appropriate when transfusing recipients with special needs?

For example:

When a mother and her infant test CMV negative, and the infant weighs less than 1200 grams at birth, units should be selected and processed to reduce the risk of cytomegalovirus (CMV) transmission. If recipients are hypoxic or acidotic, donor units should be selected which test negative for Hemoglobin S. When preparing a transfusion for an infant less than 4 months old:

- *Units should be selected that are less than 7 days old.*
- *Recipient should be tested for Rh type and ABO group using anti-A and anti-B with recipient cells only once per admission.*
- *The testing for unexpected antibodies should involve both mother and baby serum or plasma. If negative, no crossmatch is needed.*
- *If the recipient is positive for unexpected antibodies, the units selected for transfusion should be negative for the antigen, and a crossmatch performed at 37 degrees C., including anti-human globulin (AHG) phase testing?*
- *If infant has been exposed to alloantibodies to its own A or B antigens, its serum or plasma should be tested for Anti-A and Anti-B with donor or reagent red cells.*
- *If no Anti-A or Anti-B is detected, no crossmatch is needed. If Anti-A or Anti-B is detected, may transfuse with ABO compatible cells, but no crossmatch is required.*
- *No unit should be used that tests positive for unexpected antibodies.*

Does the protocol for life-threatening emergencies specify that (TS 48 – TS 54):

TS 48 E

A reasonable attempt be made to obtain a “Statement of Need” signed by the recipient’s physician, prior to release of uncrossmatched units?

Whenever possible, a written statement of need should be obtained prior to the release of uncrossmatched units for transfusion. However, there may be situations where the patient’s condition is such that this may contribute to a life threatening delay. If the laboratory elects to permit a statement of need to be signed after the fact, there must be a policy and a mechanism to ensure follow up.

TS 49 E

If it is not possible to obtain the “Statement of Need” in advance, is a mechanism in place to ensure the physician’s signature is obtained within 24 hours of the event?

TS 50 R

Group O cells are given if recipient’s blood group is unknown?

TS 51 R

Type-specific blood is given if patient’s type is known?

TS 52 R

The attached bag tag indicates that a crossmatch has not yet been completed?

TS 53 R

Compatibility testing is performed as soon as possible?

TS 54 R

Records are maintained indicating completion of crossmatches?

Blood Components With Special Handling Requirements

#TS 55-59 may be abbreviated in cases of total volume replacement within a 24 hour period.

When processed for transfusion, are units of:

TS 55 R

Fresh frozen plasma (FFP) found to be ABO compatible with recipient RBC's, especially when transfused to infants or young children depending on their clinical status?

The transfusion service must establish age and/or clinical status criteria for young children.

TS 56 R

Cryoprecipitated Anti-hemophilic Factor (AHF) found to be ABO compatible with recipient RBC's if possible, especially when transfused to infants or young children depending on their clinical status?

The transfusion service must establish age and/or clinical status criteria for young children.

TS 57 R

Random and/or Apherisis Platelets found to be ABO compatible when possible with recipients RBC's, especially when transfused to infants?

Crossmatch if >5ml of RBCs are present.

TS 58 R

Granulocytes found to be ABO-compatible with recipients plasma?

Granulocytes should be crossmatched if >5ml of RBC's are present. Leukocyte reduction filters or microaggregated filters of the depth type should not be used in the administering set.

TS 59 R

Pooled or mixed components found to be ABO-compatible with recipients plasma when RBC's are grossly visible and, when possible, plasma alloantibodies are compatible with the RBC's?

Dispensing Requirements

Prior to release for transfusion, are all units of blood and blood components:

TS 60 R

Compared for ABO/Rh type compatibility with recipient information?

TS 61 R

Checked for completeness and accuracy of recipient information?

TS 62 R

Checked for completeness and accuracy of attached label and tie tag?

This includes such things as:

- Name of product?
- Recommended temperature of storage?
- Expiration date and time if expiration is less than 72 hours?
- Name, address and identification number of facility preparing the final blood products?
- ABO group and Rh type?
- Rh is not needed if the unit is cryoAFH. Labels are color coded.
- Unexpected antibodies, if detected?
- Instructions for transfusions (i.e. current "Circular of Information for the Use of Human Blood and Blood Components")?
- The statement "This product may transmit infectious agents."?
- The statement "Caution: Federal law prohibits dispensing without a prescription."?
- The statement "IRRADIATED" if unit was irradiated to prevent complications of graft vs. host disease?
- The statement: "Negative for CMV" if tested and found to be negative for cytomegalovirus for transfusion of immune-compromised patients?
- Final unit volume and the name of the anticoagulant used?
- Name and address of transfusing facility?
- Number of units in the pool (if a pooled product)?
- Identification number record of all units in the pool (if a pooled product)?
- Designation of the unit as being from a volunteer, paid or autologous donor?
- If unit was collected for therapeutic purposes, the disease on the label?
- The statement "Properly identify intended recipient."?
- The statement "Caution: For manufacturing use only", if appropriate?
- The statement "Caution: Not for transfusion", if appropriate?
- The statement "For emergency use only by: recipient's name", if shipped in an emergency?
- Results of all tests done prior to shipment and a list of tests left undone if shipped in an emergency prior to completion of all required testing?
- Verified bar coded information?
- Blood cell antigens if donor was immunized?

If units are designated for autologous use, does the label include:

- Patient's name?
- Hospital identification number?
- Blood group and Rh type?
- Date of donation?
- The statement "For Autologous Use Only."

TS 63 R

Labeled with recipient's first and last name and identification number?

TS 64 R

Labeled with the donor unit number?

TS 65 R

Labeled with the interpretation of compatibility tests?

TS 66 R

Checked for completeness and accuracy of the donor unit record?

TS 67 R

Checked against previous results of ABO group, Rh type and previously detected antibodies for any discrepancy?

Units for Reissue

TS 68 R

Are there readily accessible written procedures in effect that detail criteria for the suitability of blood and blood components for reissue?

The procedure should specify that blood that has been returned to the blood bank or transfusion service shall not be reissued unless the following conditions have been observed:

- *The container closure has not been disturbed.*
- *The blood has not been allowed to warm above 10° C or cool below 1° C during shipping or transportation.*
- *The records indicate that the blood has been reissued, and that it has been inspected prior to reissue.*
- *At least one sealed segment of integral donor tubing has remained attached to the container. Removed segments may be reattached by confirming that the tubing identification number on both the removed segment(s) and the container are identical.*

TS 69 R

Does documentation verify that the unit was maintained at the proper temperature at all times or returned to the lab within 30 minutes?

Units should not be warmed above 10 degrees C or cooled below 1 degree C.

Prior to reissue, are returned units of blood and blood components inspected to verify that:

TS 70 R

The seal remains unbroken and sterility of the unit has been maintained?

TS 71 R

At least one segment is still attached?

Transfusion Reactions

TS 72 R

Are there readily accessible written procedures in effect that detail the protocol for investigation of suspected adverse transfusion reactions?

TS 73 R

Are blood specimens of each donor and recipient retained in accordance with written procedures for at least 7 days after transfusion to facilitate follow-up of all suspected adverse transfusion reactions?

TS 74 E

Are all suspected adverse transfusion reactions promptly and thoroughly investigated by the appropriate individuals and are the investigation documented?

Immediate reactions determined to be due to allergic reactions or circulatory overload do not require further investigation.

Does the written transfusion reaction investigation procedure and associated documentation:

TS 75 R

Include checking for errors in the identification of the recipient or in the records?

TS 76 R

Require that a new blood sample be drawn? **TS 77 R** Require that all infusion materials be collected?

TS 78 R

Include checking for hemolysis of the newly collected blood sample?

TS 79 R

Include a repeat direct antiglobulin test (DAT) that is compared to the initial sample?

TS 80 R

Include culturing for potential contamination, if clinically indicated?

TS 81 R

Recommend changes to transfusion procedures in response to identified errors?

TS 82 R

Include taking remedial action to prevent future transfusion reactions?

TS 83 R

Include a report-back mechanism to testing or collecting facility if results of adverse transfusion reactions were attributable to them?

TS 84 E

Does the laboratory have a procedure for the immediate notification of the FDA and COLA in the case of transfusion related fatalities?

The transfusing facility must notify the FDA by phone or telegraph as soon as possible, and in writing within 7 days of all transfusion-related fatalities

Record Keeping and Documentation**TS 85 E**

Does the record keeping system in use trace all units from source to disposition, facilitating the investigation of adverse reactions and facilitate recall if needed?

TS 86 R

Does the record keeping system in use identify the persons responsible at each step in the transfusion process?

Does the record keeping system in use include:

TS 87 R

A record of all reagents used when testing donor units that includes the manufacturer's name, lot number, and expiration date?

TS 88 R

The disposition of rejected reagents?

TS 89 R

A dispensing log of plasma derivatives such as Rh immune globulin, Factor VIII, Factor IX, and albumin indicating recipient and lot number?

TS 90 R**Date of receipt of recipient's specimen?****TS 91 R****A record of inspection of units before issue?****TS 92 R****A record of all reports of suspected adverse transfusion reactions, complaints, and their investigation and follow-up?****TS 93 R****A log or other mechanism to record any incidents where laboratory activities were not performed in accordance with established policy and procedures, or where the laboratory identified a problem with a blood product?**

Quality Assessment reviews must include a review of critical activities associated with the transfusion service. To facilitate this process and ensure proper investigation and monitoring of activities, there needs to be a mechanism to capture information concerning any events in which:

- *Policies or procedures were not followed, such as failure to complete a cross-match, or release of the wrong unit*
- *A problem is detected with a blood product, such as ABO/Rh type does not match label on unit, visual inspection reveals hemolysis or clots present in the unit.*

TS 94 R**If you ship or transport blood and blood components from your facility to another, are distribution records maintained that indicate name and address of consignees?****TS 95 R****If you ship or transport blood and blood components from your facility to another, are distribution records maintained that indicate date and quantity being sent?****TS 96 R****If you ship or transport blood and blood components from your facility to another, are distribution records maintained that indicate donor number, component type (i.e. RBCS, leuko-poor RBCS, FFP, Platelets, Cryoprecipitate), and ABO/Rh type of the component?****TS 97 R****If you ship or transport blood and blood components from your facility to another, are distribution records maintained that indicate expiration or collection dates, whichever is applicable?****TS 98 R****If you ship or transport blood and blood components from your facility to another, are distribution records maintained that indicate name of recipient, if crossmatched?**

When the laboratory receives units of blood and blood components, are records of receipt maintained that include:

TS 99 R

The name and address of the collection facility?

TS 100 R

Date received?

TS 101 R

Donor number, component type (i.e. RBCS, leuko-poor RBCS, FFP, Platelets, Cryoprecipitate), and ABO / Rh type of the component?

TS 102 R

Expiration or collection dates, whichever is applicable?

Record Retention

TS 103 R

Does the laboratory retain all transfusion-related documentation for the length of time specified by the FDA at 21 CFR 606, Subpart I?

Retain all records beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. Retention period shall be:

- *Ten years from the date that processing was complete, or*
- *Six months after the latest expiration date for individual products, whichever is later;*
- *Otherwise, records should be retained indefinitely.*

NOTES



IN THIS SECTION

Educational Resources and Support from COLA Resources, Inc. (CRI)

LabUniversity® Online Continuing Education	159
Laboratory Director CME Program for Physicians.....	160
Symposium for Clinical Laboratories™	160
Educational Publications and Products	160
Continuous Quality Program	160
Other Internet Resources.....	161

COLA Resources, Inc. (CRI) is a subsidiary of COLA that provides educational and consultative services aimed at improving laboratory medicine and patient care.

CRI offers many educational opportunities for physicians, laboratory scientists, and laboratory professionals aimed at enhancing professional knowledge, assisting in improving laboratory operations and patient care.

CRI offers online continuing education courses on various laboratory topics through our www.LabUniversity.org and www.CRledu.org websites. Augmenting our online educational offerings are LIVE webinars and Symposiums, along with a variety of downloadable publications.

LabUniversity® Highly Regarded, Convenient, Comprehensive Online Continuing Education

LabUniversity® is CRI's online distance learning center developed to respond to the needs of busy physicians and laboratory staff. Courses and programs are convenient to use and are designed to meet continuing education, certification, and licensing requirements.

The online courses offer flexibility as they are accessible at anytime, anywhere where Internet access is available. Courses include examples drawn from current laboratory practices and provide additional resources on the topic – offering practical knowledge that can be immediately applied to laboratory practices.

CRI's courses for laboratory professionals in the clinical laboratory are approved by the ASCLS P.A.C.E.® Program, the Florida Agency for Health Care Administration, and the California Division of Laboratory Science, Department of Laboratory Field Services.



For More Information About All CRI Educational Offerings

To learn more about CRI's educational programs, from online continuing education courses to publications and symposiums, visit our websites: www.labuniversity.org, or www.CRledu.org, or e-mail LabUniversity@cola.org.

Laboratory Director CME Program for Physicians

CRI provides physicians an opportunity to earn the Continuing Medical Education (CME) credits needed to meet CLIA requirements to be director of a moderate complexity laboratory. The LD Program incorporates the CMS-required topics of laboratory practice and director responsibilities.

Through this program, which combines interactive exercises with self-paced learning activities in a flexible, online format, physicians can learn basic and advanced skills needed to successfully direct a moderate complexity laboratory.

CRI's physician education courses provide CME credit through the American Academy of Family Physicians (AAFP).

Symposium for Clinical Laboratories™

CRI hosts interactive live symposiums around the country each year for physicians and healthcare professionals. Whether working in a hospital, reference laboratory, or a physician's office, the Symposium is an ideal venue for accessing education in laboratory medicine, for all levels of laboratory personnel.

Educational Publications and Products

CRI offers a variety of publications that meet the needs of laboratory professionals, including:

- *IQCP (Individualized Quality Control Plan)*: Program offered in various learning platforms (on-line or hard copy) including various components aimed at assisting in the understanding, development and implementation of an IQCP for the clinical laboratory.
- *Quality Assessment Plan, A Simplified Approach*: A turn-key publication which includes a working template of a QA plan for any laboratory to implement immediately.
- *OSHA Self-Assessment*: Guide to Complying with the OSHA Bloodborne Pathogen Regulations Provides a complete overview of the bloodborne pathogen regulations and requirements.
- *CLIA Fact Sheets* User-friendly reference sheets relating to CLIA requirements for quality assessment, quality control, personnel standards, and proficiency testing. #
- *LabGuides* -Easy to use guides on a variety of medical laboratory topics including testing specialties, proficiency testing, quality control, quality assessment, and regulatory matters.

For more information about CRI educational offerings, please visit www.LabUniversity.org or www.CRledu.org or call (800) 981-9883.

Continuous Quality Program

Traditionally, laboratory quality has been measured by compliance with federal and state regulations, and periodically enforced through biennial surveys. But these surveys represent only a snapshot of lab quality at any given time. The real challenge is to help laboratorians integrate quality policies and procedures into their daily lives. That's why CRI has initiated the Continuous Quality Program, based on achieving a sustainable culture of quality, which permeates all aspects of the laboratory operation on a daily basis. Our Continuous Quality Advisors (CQAs) will partner with laboratories whenever technical, operational, regulatory, or personnel issues and concerns need to be addressed. We offer direct telephone and email advice, relevant educational products, and consultancy services to help laboratories achieve their goal of quality patient care.

Other Internet Resources

The following links will serve as useful resources in your laboratory operations and accreditation activities.
Clinical Laboratory Improvement Amendments of 1988 (CLIA)

<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/>

American Association of Blood Banks (AABB) Standards for Blood Banks and Transfusion Services

www.aabb.org

Occupational Safety and Health Administration (OSHA)

www.osha.gov

Americans with Disabilities Act (ADA)

www.ada.gov

Environmental Protection Agency (EPA)

www.epa.gov

Centers for Disease Control (CDC)

www.cdc.gov

Department of Transportation (DOT) For transport of hazardous materials

www.dot.gov

Clinical and Laboratory Standards Institute (CLSI)

www.clsi.org

Food and Drug Administration (FDA)

www.fda.gov

COLA Accreditation Manual—Revision No.12, June 2013. ISODOC 53-16. In keeping with the ever changing healthcare environment, COLA Accreditation Policy is subject to change. Published by COLA, 9881 Broken Land Parkway, Suite 200, Columbia, MD, 21046-1195; (800) 981-9883; Fax: (410) 381-8611

This manual is one of the many benefits of enrolling in a COLA accreditation program for laboratories. Copies of this manual are available for purchase. Call (800) 981-9883 or visit www.LabUniversity.org to order.

This manual is protected by copyright. No part of it may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or by any information storage and retrieval system without permission in writing.

ALL RIGHTS RESERVED.



IN THIS SECTION

CMS Approved Proficiency Testing Providers.....	162
Personnel Requirements.....	163
FDA Record Retention for Blood and Blood Products.....	166

CMS Approved Proficiency Testing Providers (as of April 2012)

COLA will recognize any PT program with whom we have entered into an agreement to exchange data and is approved by CMS. Follows is the list of approved proficiency testing providers meeting these criteria. Further details about approved proficiency testing providers can also be found at the CMS website.

ACCUTEST, Inc.

P.O. Box 999
Westford, MA 01886-0031
(800) 665-2575 | www.accutest.org

AAFP-PT

American Academy of Family Physicians
11400 Tomahawk Creek Parkway
Leawood, KS 66211-2672
(800) 274-7911 | www.aafp.org/pt

AAB-PT

American Association of Bioanalysts
205 West Levee Brownsville, TX 78520
(800) 234-5315 | www.aab.org/pts/pts.htm

ACP-MLE

American College of Physicians-Medical Laboratory
Evaluation (MLE)
25 Massachusetts Ave. NW Suite 700
Washington, DC 20001-7401
(800) 338-2746 | www.acponline.org/mle

API

American Proficiency Institute
1159 Business Park Drive
Traverse City, MI 49686
(800) 333-0958 | www.api-pt.com

California Thoracic Society

575 Market St. Suite 2125
San Francisco, CA 94105
(415) 536-0287 | email: info@calthoracic.org

CAP Excel/Surveys

The College of American Pathologists
325 Waukegan Rd.
Northfield, IL 60093-2750
(800) 323-4040 | www.cap.org

Commonwealth of Pennsylvania*

Department of Health, Bureau of Laboratories
P.O. Box 500
Exton, PA 19341-0500
(610) 280-3464

*Toxicology only- blood alcohol and blood lead

Dept. of Health of Puerto Rico Laboratory Services Program

PT Services, P.O. Box 70184, Bldg. A
San Juan, PR 00936-8184
(787) 274-6827

New York State Department of Health

The Governor Nelson A. Rockefeller State Plaza
P.O. Box 509
Albany, NY 12201-0509
(518) 474-8739

WSLH Proficiency Testing

Wisconsin State Laboratory of Hygiene
465 Henry Mall Madison, WI 53706-1578
(800) 462-5261 | (608) 833-5222 | www.wslhpt.org

PERSONNEL REQUIREMENTS

NOTE: All individuals must have all required state licenses for all positions held – pertains to the state where the lab is located

MODERATE COMPLEXITY LABORATORIES

DIRECTOR	TECHNICAL CONSULTANT	CLINICAL CONSULTANT
<ol style="list-style-type: none"> 1. Licensed MD/DO/DPM, AND certified in anatomic or clinical pathology, OR lab training or experience consisting of 1 year directing or supervising non-waived tests, OR Beginning 09/01/1993, have earned at least 20 CME credits in laboratory practice addressing director responsibilities, OR training equivalent to 20 CME credits obtained during medical residency. 2. Doctoral degree in laboratory science AND certified by an HHS-approved Board, OR have 1 year experience directing or supervising non-waived testing. 3. Master's degree in lab science AND 1 year lab training or experience AND 1 year of experience supervising non-waived testing. 4. Bachelor's degree in lab science AND 2 years lab training or experience AND 2 years experience supervising non-waived testing. 5. Prior to 02/28/1992, qualified as Director under state law or Medicare lab regulations. 	<ol style="list-style-type: none"> 1. Licensed MD/DO/DPM AND certified in anatomic or clinical pathology OR 1 year lab training or experience in non-waived specialty/subspecialty of service. 2. Doctoral or Master's degree in laboratory science AND 1 year lab training or experience in the non-waived specialty / subspecialty of service. 3. Bachelor's degree in laboratory science AND 2 years lab training or experience in the non-waived specialty / subspecialty of service <p>NOTE: "Training or experience" in specialties and subspecialties can be acquired concurrently.</p>	<ol style="list-style-type: none"> 1. Licensed MD/DO/DPM. 2. Doctoral degree in laboratory science AND board certified in specialty/subspecialty of service. <h4>TESTING PERSONNEL</h4> <ol style="list-style-type: none"> 1. Licensed MD/DO/DPM 2. Doctoral, Master's, Bachelor's, or Associate's degree in laboratory science 3. High School graduate or equivalent AND completed military Medical Lab Specialist (50 week) course. 4. High School graduate or equivalent AND documentation of training at the present facility for testing performed.

HIGH COMPLEXITY LABORATORIES

DIRECTOR	TECHNICAL SUPERVISOR	GENERAL SUPERVISOR
<p>1. Licensed MD/DO/DPM AND certified in anatomic or clinical pathology OR 1 year of lab training during medical residency OR 2 years experience directing or supervising high complexity testing.</p> <p>2. Doctoral degree in laboratory science AND certified by an HHS-approved board OR prior to 02/24/2003, served as Lab Director AND 2 years lab training or experience AND 2 years experience supervising or directing high complexity testing.</p> <p>3. Prior to 02/28/1992, qualified as Lab Director under state law or Medicare lab regulations.</p> <p>TESTING PERSONNEL</p> <p>1. Licensed MD/DO/DPM.</p> <p>2. Doctoral, Master's, Bachelor's or Associate's degree in laboratory science.</p> <p>3. Have education equivalent to an Associate's degree AND graduated from a clinical laboratory training program OR have 3 months experience in each specialty of high complexity testing performed.</p> <p>4. Prior to 04/24/1995, High School graduate or equivalent AND graduated from an HHS-approved lab training program OR completed military Medical Lab Specialist (50 week) course.</p> <p>5. Prior to 04/24/1995, High School graduate or equivalent AND documentation of training for high complexity testing AND if training before 01/19/93, on-site supervision is required when high complexity testing is performed.</p> <p>NOTE: Must also provide documentation of training at the present facility for testing personnel</p> <p>For Blood Gases: If not qualified above: Bachelor's or Associate's degree in respiratory therapy, pulmonary function, or cardiovascular technology</p>	<p>Specific qualifications are required for each specialty or subspecialty.</p> <p>For Microbiology subspecialties – bacteriology, mycobacteriology, mycology, virology, and parasitology:</p> <p>1. Licensed MD/DO/DPM or PhD AND certified in clinical pathology OR 1 year lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service.</p> <p>2. Master's degree in laboratory science AND 2 years lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service.</p> <p>3. Bachelor's degree in laboratory science AND 4 years lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service.</p> <p>For Immunology, Chemistry, Hematology, or Radiobiology:</p> <p>1. Licensed MD/DO/DPM or PhD AND certified in clinical pathology OR 1 year lab training or experience in the high complexity testing specialties performed</p> <p>2. Master's degree in lab science AND 2 years lab training or experience in the high complexity testing specialties performed.</p> <p>3. Bachelor's degree in lab science AND 4 years lab training or experience in the high complexity testing specialties performed.</p> <p>For Immunochemistry:</p> <p>Licensed MD/DO/DPM AND certified in clinical pathology OR 1 year lab training or experience in immunochemistry testing.</p> <p>CLINICAL CONSULTANT</p> <p>1. Licensed MD/DO/DPM.</p> <p>2. Doctoral degree in lab science AND board certified in specialty/subspecialty of service...</p>	<p>1. Qualified Lab Director or Technical Supervisor of high complexity testing.</p> <p>2. Licensed MD/DO/DPM, or have a Doctoral, Master's, or Bachelor's degree in lab science AND 1 year laboratory training or experience in high complexity testing.</p> <p>3. Qualified as Testing Personnel for high complexity testing AND at least 2 years laboratory training or experience in high complexity testing.</p> <p>4. Previously qualified as General Supervisor on or before 02/28/1992.</p> <p>5. Prior to 09/01/1992, served as General Supervisor of high complexity testing AND prior to 04/24/95 completed military Medical Lab Specialist (50 week course) AND had at least 2 years lab training or experience in high complexity testing OR graduated from an HHS-approved lab training program AND had at least 2 years lab training or experience in high complexity testing</p> <p>6. Prior to 09/01/1992, served as General Supervisor of high complexity testing AND have a high school diploma or equivalent AND more than 10 years experience in high complexity testing including at least 6 years supervisory experience from 09/01/1982 to 09/01/1992.</p> <p>7. Prior to 09/01/1992, served as General Supervisor of high complexity testing and prior to 01/01/1994: passed an HHS approved technical proficiency exam given between 03/01/1986 and 12/31/1987 AND have 6 years lab training or experience with 2 years in high complexity testing specialties.</p> <p>For Blood Gases: if not qualified above:</p> <p>1. BA/BS in respiratory therapy, or cardiovascular technology AND 1 year training or experience</p> <p>2. AA/AS related to pulmonary function AND 2 years training or experience.</p>

NOTES

Code of Federal Regulations Title 21, Volume 7 Revised as of April 1, 2012

CITE: 21 CFR 606 Title 21 – Food and Drugs Chapter I – Food and Drug Administration Department of Health and Human Services Subchapter F – Biologics Part 606 – Current Good Manufacturing Practices for Blood and Blood Components

Subpart I – Records and Reports

606.160 Records

- (a) (1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.
- (2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product. (b) Records shall be maintained that include, but are not limited to, the following when applicable: (1) Donor records:
- (i) Donor selection, including medical interview and examination and where applicable, informed consent. (ii) Permanent and temporary deferrals for health reasons including reason(s) for deferral. (iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.
 - (iv) Therapeutic bleedings, including signed requests from attending physicians, the donor's disease and disposition of units.
 - (v) Immunization, including informed consent, identification of the antigen, dosage and route of administration. (vi) Blood collection, including identification of the phlebotomist. (vii) Records to relate the donor with the unit number of each previous donation from that donor. (viii) Records concerning the following activities performed under §§ 610.46, 610.47, and 610.48 of this chapter: Quarantine; consignee notification; testing; notification of a transfusion recipient, the recipient's physician of record, or the recipient's legal representative; and disposition.
 - (ix) Records of notification of donors deferred or determined not to be suitable for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.6 of this chapter. (x) The donor's address provided at the time of donation where the donor may be contacted within 8 weeks after donation. (xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial notification attempt fails, performed under § 630.6 of this chapter.
- (2) Processing records:
- (i) Blood processing, including results and interpretation of all tests and retests.
 - (ii) Component preparation, including all relevant dates and times.
 - (iii) Separation and pooling of recovered plasma.
 - (iv) Centrifugation and pooling of source plasma.
 - (v) Labeling, including initials of the person(s) performing the procedure.

(3) Storage and distribution records:

(i) Distribution and disposition, as appropriate, of blood and blood products. (ii) Visual inspection of whole blood and red blood cells during storage and immediately before distribution. (iii) Storage temperature, including initialed temperature recorder charts. (iv) Reissue, including records of proper temperature maintenance. (v) Emergency release of blood, including signature of requesting physician obtained before or after release.

(4) Compatibility test records: (i) Results of all compatibility tests, including crossmatching, testing of patient samples, antibody screening and identification. (ii) Results of confirmatory testing.

(5) Quality control records: (i) Calibration and standardization of equipment. (ii) Performance checks of equipment and reagents. (iii) Periodic check on sterile technique. (iv) Periodic tests of capacity of shipping containers to maintain proper temperature in transit. (v) Proficiency test results.

(6) Transfusion reaction reports and complaints, including records of investigations and followup. (7) General records:

(i) Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature and mode. (ii) Responsible personnel. (iii) Biological product deviations. (iv) Maintenance records for equipment and general physical plant.

(v) Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt. (vi) Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components. (c) A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood, and to all records describing the history and ultimate disposition of these products. (d) Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely. (e) A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.

[40 FR 53532, Nov. 18, 1975, as amended at 61 FR 47422, Sept. 9, 1996; 64 FR 45371, Aug. 19, 1999; 65 FR 66635, Nov. 7, 2000; 66 FR 31176, June 11, 2001; 72 FR 48798, Aug. 24, 2007

606.165

Distribution and receipt; procedures and records. (a) Distribution and receipt procedures shall include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall, if necessary. (b) Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit(s), the date of expiration or the date of collection, whichever is applicable, or for crossmatched blood and blood components, the name of the recipient. (c) Receipt records shall contain the name and address of the collecting facility, date received, donor or lot number assigned by the collecting facility and the date of expiration or the date of collection, whichever is applicable.

606.170

Adverse reaction file. Link to an amendment published at 77 FR 18, Jan. 3, 2012.

- (a) Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of blood collection or transfusion. A thorough investigation of each reported adverse reaction shall be made. A written report of the investigation of adverse reactions, including conclusions and followup, shall be prepared and maintained as part of the record for that lot or unit of final product by the collecting or transfusing facility. When it is determined that the product was at fault in causing a transfusion reaction, copies of all such written reports shall be forwarded to and maintained by the manufacturer or collecting facility.
- (b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, shall be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

[40 FR 53532, Nov. 18, 1975, as amended at 49 FR 23833, June 8, 1984; 50 FR 35471, Aug. 30, 1985; 55 FR 11014, Mar. 26, 1990; 64 FR 45371, Aug. 19, 1999; 67 FR 9586, Mar. 4, 2002; 77 FR 18, Jan. 3, 2012]