THE *NEW* POOR LAB'S GUIDE TO THE REGULATIONS

(CLIA, The Joint Commission, CAP & COLA)

2025 – 2026

Successful Strategies & Specific Applications of the Regulations

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Foreword by Delia Gates, MT(ASCP)

I had the opportunity to meet Dr. Sharon Ehrmeyer in May of 2010 when she was a speaker at a 3-day "Westgard Workshop" on Quality Control practices and planning in Madison, Wisconsin. Her presentations featured QC in the real world and expert advice on accreditation requirements. When her 2012 edition of the "New" *Poor Lab's Guide* was published, I found it to be a clear and useful companion to navigating government regulations. Thus began my collection of successive editions whose pages have been read, re-read, highlighted and flagged with sticky notes.

My career in clinical laboratory science began a decade prior to CLIA '88, at the teaching hospital where I had attended MT school, moonlighting in POLs on the side. Life's path led to small hospitals as a generalist, to a state hospital in RIA and toxicology, to a primate center in virology research as HIV study was emerging. Eventually I turned to diagnostic manufacturers of chemistry and immunochemistry for the technical applications and customer support experience.

Currently I enjoy my role as field specialist and trainer for a clinical chemistry manufacturer whose clientele are veterinary hospitals, research and pharmaceutical companies, MLT educational settings, plus CLIA labs in the smaller hospital, urgent care and physician office practices. The majority of customers I visit are POLs, who may have no prior lab experience and are most in need of guidance.

It is exciting to serve as a resource for my customers and colleagues, where the *Poor Lab's Guide*, over the years, has been a primary reference. Even if you're a laboratorian with more than a few inspections and PT events under your belt, there is something you haven't encountered in the notes, excerpts from the Interpretive Guidelines, Do's and Don'ts, FAQs, sample forms and inspection survival tips. It delights me to recommend the *"New" Poor Lab's Guide to the Regulations*. I offer this advice, if I may: Don't "do lab" without it!

Delia Gates, MT(ASCP)
Account Manager, Alfa Wassermann Diagnostic Technologies

Foreword by Diane Davis, MT(ASCP)SH

As a young technologist and newly minted supervisor, I struggled to find a concise guide to the many rules, regulations, and procedures I needed to know in order to run my lab according to "best practices." In my experience, the standards published by various regulatory bodies were opaque, conclusory, and difficult to navigate; moreover, these materials offered little in the way of *practical* guidance for end users. I quickly learned that seemingly simple questions (e.g., "How closely should between-analyzer correlations match?" and, "Is it okay to use quality controls to determine accuracy of a new method?") often had surprisingly complex answers. I acquired these answers over the years by exchanging anecdotes with peers, soliciting advice from mentors, and reading a variety of books unearthed in the course of my own research, but it proved to be a slow and laborious process of accumulation that only intermittently yielded the critical knowledge that diligent practitioners should have at their disposal.

When I discovered *The Poor Lab's Guide* in 2012, it was nothing short of a revelation. At the time, I was working as a manager in a hospital laboratory, and the *Guide* was precisely the resource I had sought in vain at the beginning of my laboratory career. Here it was: one-stop shopping for all of the answers to those nagging and complicated questions that had once plagued me, and have since tormented so many others in our field. While packing up my home office to move to a new home, I recently rediscovered that very first copy, with all of the tabbed pages that I zealously marked for my important references. *The Poor Lab's Guide* has not lost any of its extraordinary utility over the years; as regulations have changed, the Guide has been updated to reflect the most recent directives. It truly is a "living document," and I have purchased a copy of each and every update without hesitation or regret.

In 2014, I became a manager and subsequently a director for an in-vitro diagnostic company, leading a team of Applications Specialists. My team and I routinely encounter customers who are supervisors and managers in hospital laboratories who have all of the same questions that I did as a new supervisor, and who have similarly struggled to find a succinct, definitive reference guide for

regulatory compliance. As a vendor, we are not in a position to make decisions for laboratories, but we are frequently asked for advice. I have provided each of the Applications Specialists on my team with a copy of the *Guide*, which has proven itself to be an invaluable resource that enables us to competently and confidently provide our customers with up-to-date guidance, regardless of the regulatory organization that accredits a particular laboratory.

I continue to provide *The Poor Lab's Guide* for my team, and recommend that all laboratorians consider this a "must-have" resource. For me, there will always be a copy at my desk.

Diane Davis MT(ASCP)SH

Director, Clinical Applications, Werfen

Preface

In the early 1990's, Dr. Ron Laessig and I often found ourselves teaching courses or giving lectures on the newly emerging federal regulations. They were based on the 1988 federal law, the "Clinical Laboratory Improvement Amendments of 1988" (CLIA'88 or CLIA) for short.

In 2003 CLIA was revised and in 2004, CMS published Appendix C of the State Operations Manual, *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services*, which "interprets" the CLIA'03 regulations for both inspectors and laboratories. And, the CMS-deemed accreditation agencies continually "tweaked" their requirements along the way. This *Poor Man's Guide* is up to date with CLIA regulations along with the latest requirements for CAP, The Joint Commission and COLA.

Various organizations asked us to repeat the presentations because of the significant implications for laboratories and the complexity of the regulations. We initially arranged our lecture notes in a series of booklets that were later pulled together into a single volume for our AACC, ASCP, etc., workshops. Now the information is continuously updated.

One objective in compiling these materials was to give the reader an easy to understand, practical means of addressing the complexities of the CLIA regulations as well as the testing requirements from the CMS-deemed accreditation agencies. I

For the record, Dr. Ronald Laessig conceived of the idea for what is now "THE NEW POOR LAB'S GUIDE TO THE REGULATIONS: CLIA, The Joint Commission, CAP & COLA." The name came out of the concept of extending the calibration beyond the highest calibrator using a patient specimen with an appropriately elevated result. Since the technique did not cost much (it's actually free), this approach led to the working title of "Poor Man's Guide." I insisted on making the document politically correct and added "Person's" to the title. For the sake of simplicity, we changed from the NEW POOR MAN'S (PERSON'S) GUIDE to the more concise (and neutral) POOR LAB'S GUIDE.

The earlier editions included the disclaimer that no federal, state or professional inspector, company or professional organization necessarily agreed with what we said or endorsed our approach. It still holds! However, it should be noted that on more than one occasion inspectors have suggested, during the inspections, this Guide as a practical way to understanding the myriad of complexities associated with implementing the regulations.

Finally, special thanks go to a friend, mentor and colleague, Dr. Laessig who died unexpectedly, but peacefully, in his sleep on March 29, 2009. Ron enriched my life immensely and, like me, those he touched miss him tremendously.

Sharon Ehrmeyer, PhD

Table of Contents

What's new in the 2025 Edition

While labs breathed collective relief when the FDA Laboratory-Developed Test (LDT) regulations were vacated in court in early 2025, there were still major changes making an impact this year. In December 2023, CLIA changed its personnel qualification requirements, significantly increasing the demands for laboratory directors, etc. Then, in June 2025, it changed those qualification requirements *again*. Some of the changes cancelled each other out, others merely added to the confusion. We have completely updated the Personnel chapter to reflect the combined impact of these new requirements.

Labs may be relieved to see that there isn't a chapter dedicated to the LDT FDA regulations, but that doesn't mean your LDT tests are "free" from any regulation or inspection. LDTs, in the absence of specific regulations, fall under the CLIA category of high complexity and continue to require the most extensive validation and competencies.

Of course, all updates from the accreditation organizations, from The Joint Commission (TJC), to the College of American Pathologists (CAP), and COLA are described and discussed in detail.

All this and more is covered in the 2025-2026 edition of the *Poor Lab's Guide*.

Tribute to Ron Laessig

Ron Laessig was Emeritus Director of the Wisconsin State Laboratory of Hygiene and Emeritus Professor of Population Health Sciences (and he liked to say "sometimes clinical chemist") at the University of Wisconsin Medical School. He retired after over 40 years of service to the University and the State of Wisconsin.

The best description of Ron is a "quality builder." And there were many dimensions to his building, from furniture to his home, from clinical chemist to Director of a large testing service, from proficiency testing to total quality management, from in-service training to statewide training seminars, from classroom instruction to national workshops, from committee member to President of NCCLS (now CLSI), from staff building to a new laboratory building that represents the state-of-the-art in environmental and toxicology testing in the US today.

I met Ron in graduate school where we shared a research laboratory. Two memories stand out – coffee that would make your hair stand on end and a work schedule that began at 6:00 am and went until at least 12 midnight, 6 days a week. Having come from ND and grown up working on a farm, I always believed that I had a strong work ethic and could outwork almost everyone. But not Ron! I don't think anyone had the dedication and commitment that he showed as a graduate student and throughout his career. And his accomplishments reflect that willingness to work hard at everything he did!

Our careers started out in a parallel fashion, beginning as clinical chemists in different labs of the University of Wisconsin, but we diverged as Ron acquired more and more management and leadership responsibilities at the State Lab and nationally, while I became more specialized in Quality Control. Yet things also converged at certain periods in time, such as when Ron mentored Sharon Ehrmeyer in her graduate program on External Quality Control, or Proficiency Testing, which paralleled some of my own studies in Internal Quality Control. Ron and Sharon maintained an ongoing collaboration and were spurred on by the laboratory regulatory environment. They co-authored this "Poor Man's Guide" which explained the regulations in a down-to-earth manner to help

laboratories adapt to the "CLIA rules." With the advent of the Final CLIA rule in 2003, our interests again converged in opposition to CMS's proposed "equivalent QC" guidelines. And Ron enjoyed it when CMS admitted they "blew it," as Ron and Sharon discussed in an editorial in *Lab Medicine* in October 2005.

Ron always had fun in whatever he was doing! That was part of his formula for life. He liked to tell stories and I can testify that he was very good at it, since I was sometimes on the receiving end of those stories. My worst fear was to have him precede me on a program and have to adjust my presentation on the fly to respond to his statements, such as "…enjoy this because Jim is going to be as dry as cornflakes without milk" or "…Jim will tell you more about that" (and usually mentioned a topic I knew nothing about).

It is a distinct privilege to be able to continue Ron's work in the form of this Poor Lab's Guide. While we have now published five editions since his passing, Ron's spirit still guides this manual. And while I might not agree with everything he and Sharon recommend, I do not dispute the usefulness of having this easy-to-read guide to the labyrinth of regulations, standards, accreditation guidelines that face laboratories in the US.

James O. Westgard, PhD

1: Regulations - An Overview

Historical View of Laboratory Regulations

The first national requirements regulating laboratories were issued as the Clinical Laboratory Improvement Act of 1967. These were followed closely by the Medicare regulations. The individual states and the College of American Pathologists (CAP) provided the major inspection programs.

Beginning with Dr. Sunderman and his pathology colleagues in 1945, and thanks to the CAP's efforts soon thereafter, proficiency testing (PT) programs by states and professional organizations provided a means of documenting the quality of laboratory performance. The state and federal programs monitoring laboratories incorporated PT into the regulatory process. Today, PT is a cornerstone of CLIA – successful participation is a primary indicator of quality in laboratories performing moderate and highly complex tests. These two complexity levels are now combined into the nonwaived category.

Note: The complexity category of test methods is assigned by the FDA based on seven (CLIA §493.17) measures of what is necessary for test performance -- knowledge; training and experience; reagents and materials preparation; characteristics of operational steps; calibration, quality control, and proficiency testing materials; test system troubleshooting and equipment maintenance; and interpretation and judgment. Most test methods are classified as moderate.

The CLIA'67 and Medicare regulations covered only a small percentage of U.S. laboratories (basically large hospitals and reference laboratories). The Clinical Laboratory Improvement Amendments (CLIA), replaced these regulations. On February 28, 1992, the Health Care Financing Administration (HCFA) [now renamed the Centers for Medicare and Medicaid Services (CMS)], working with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), published the requirements covering all test sites needing to meet CLIA regulations. Since February 28, 1992, the government has made changes to the regulations published in

a series of Federal Registers. The most up to date electronic edition of CLIA includes all changes, can be found at:

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

[An index for the updated (1/2025) CLIA regulations is shown in Section 1.1.]

CLIA is unique in that it requires every testing site examining *"materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease..."* to be regulated. This means that regardless of location, all clinical laboratories (testing sites) are subject to the CLIA regulations and testing must be conducted under an appropriate CLIA certificate.

As of March 2024, approximately 318,000 laboratories were registered under CLIA. CLIA requires all laboratories to have a certificate appropriate for the complexity of testing performed.

	# of Labs	#ofPOLs
Total labs registered	317,545	122,451
Total labs registered in non-exempt states	303,010	119,900
Moderate & high complexity (CMS inspected labs)	16,643	4,499
Accredited Labs (CAP, TJC, COLA, etc.)	15,894	9,974
Provider-Performed Microscopy (PPM)	25,682	19,313
Waived testing only	243,981	85,256

CLIA Certificates

CMS requires all entities to have a CLIA certificate to perform even one test, including waived tests on "materials derived from the human body for the purpose of providing information for the diagnosis,

2: Proficiency Testing for Nonwaived Testing

Proficiency Testing (PT), or External Quality Assessment (EQA), as the rest of the world knows the process, is a mechanism for evaluating laboratory performance. Beginning in the 1940's, the College of American Pathologists program showed that voluntary interlaboratory PT participation identified problems, directed improvement efforts, and steadily improved the quality of test results. Because of the benefits, CMS made PT a cornerstone of CLIA for accuracy assessment of more than 80 analytes, generally referred to as **regulated analytes**. All laboratories performing nonwaived test methods MUST at least participate in PT for these regulated analytes and follow the CLIA rules described below. This includes labs seeking accreditation from a CLIA-deemed accreditation organization. Testing performed under a Certificate of Waiver are exempt. Following ALL the rules is imperative! PT Failures continue to be one of the top 10 problems that labs experience.

On July 11, 2022, The Federal Register updated CLIA's proficiency testing criteria. This represents the BIGGEST change in regulations since 1992. These regulations officially took effect on July 11, 2024, but practically, they only took effect on January 1st, 2025, when CAP and other PT providers began enforcing the new criteria.

These changes include:

- Addition/deletion of regulated analytes requiring PT participation;
- Changes (§§ 493.2 and 493.801 through 493.959) to acceptable performance limits and updates to the administrative processes for approved PT providers;
- Alignment to statute (42 U.S.C. 263a (i)(4)) on improper PT referral; and,
- PT requirement revisions for microbiology analytes.

While the changes won't be implemented for several months, we have included in Section 2.4, both the current regulated analytes and acceptable performance limits as well as the new analytes and their acceptable performance limits. **Note: Some of the new ac-**

ceptable limits are significantly tighter, between 20 and 41% smaller, than the limits from 1992.

Section 2.7 further discuss the 2025 changes so your lab can be ready.

The Poor Lab's View of the Rules

1. **PT Participation:** All laboratories performing nonwaived testing (moderate and high complexity tests) must be enrolled in regulatory PT for each CLIA "regulated" analyte in each specialty/subspecialty of testing performed (see section 2.4). If you are new to PT, see Section 2.2 and 2.3 for an overview of PT issues and a summary of the PT process.

Note: Laboratories must participate in the same program(s) for three events (one year) before switching to another program. The PT program must be approved by CMS and laboratories must authorize the release of data to authorized agencies.

Splitting analytes over more than one PT program (i.e., CAP and the WSLH, Wisconsin State Lab of Hygiene) is acceptable. PT providers report grades to CMS on an analyte-by-analyte basis. (See Section 2.6 for interpretation of a CAP-type PT report)

In previous editions of this Guide, we suggested that laboratories sign up for additional regulatory PT programs and use the samples for internal quality assessment purposes only. ***Now*** this practice may result in a misunderstanding and could be viewed as a potential *violation* by CMS. Be careful! If this additional QA information is desired, use a *completely different* PT product other than what is used for regulatory purposes, and analyze the samples at different times than the regulatory PT time frame.

As a quality assessment alternative, CAP has introduced Quality Check programs. Some manufacturers of instruments also provide voluntary, "PT-like" quality assessment programs for their customers. These programs are excellent tools to assess quality for nonregulated analytes. CLIA's §493.1236 states that twice each year laboratories must establish the accuracy of the testing

3: Procedure Manual

Concept: At least for every nonwaived test procedure performed by the laboratory or at point of care, there must be a written and available set of instructions. (Standard Operating Procedures or SOPs) describing how to perform the test. CLIA's term for this is "Procedure Manual (PM)." Note: Some accrediting agencies may require a PM for waived and PPM testing as well. Check with your accrediting agency.

Procedure Manuals from "A to Z" or "Alpha to Omega": Laboratories need a Procedure Manual (PM) for **all** laboratory operations and **all** testing performed in the laboratory. These can be organized in one or several PMs to best fit the situation. While the testing process begins with ordering the test, the Procedure Manual (PM) begins with patient preparation and sample acquisition, extends to sample processing and analysis, and concludes with reporting results and archiving results and specimen. These stages of testing are referred to as pre-analytic (exam), analytic (exam) and post-analytic (exam) processes in the PM.

ISO15189:2022, the worldwide standard for laboratory testing, clearly summarizes the intent of having a PM: to ensure the consistent application of laboratory activities and test result validity.

The basic principles of Procedure Manuals (all you ever wanted to know)

- Prepare one for every test and have it available for the staff. Electronic copies are acceptable.
- Follow the CLIA mandates (pages 55-57) for preparation.
- Use the 16 suggestions (pages 59 through 61) in the self-assessment checklist.
- Include the manufacturer directions (package inserts) as part of your lab's PM to the extent possible for the analytical phase of testing (about 90% of the PM); add your lab/organization-specific information (10%) and you are done.

- Keep Current:
  - For CLIA, the current director must approve any new PM and any changes made.
  - Laboratories not inspected by CMS for CLIA compliance must adhere to their specific accrediting agency directives and director approval/review signature requirements. Follow your accrediting organization's requirements.
  - Manufacturer product inserts MUST match the lot of product in current use.
  - The PM must be part of the initial orientation to testing and annual competency assessment for personnel.
- Maintain a copy of each procedure with the dates of initial use and discontinuance.
- **Keep the Master Secure:** The content of the master PM must be controlled. Only authorized persons are allowed to make changes. When changes are made, staff always must follow the latest version.

Life's most important secret (about PM's): Write and construct the manual to fit your laboratory's circumstances. Write for your typical employee, i.e., a clinical laboratory scientist.

Procedure Manual Example:

"Controls for the test XYZ evaluate accuracy, monitor precision and are kept in the refrigerator in the N.E. corner of room 416. Reconstitute with a 5.0 ml volumetric pipette using distilled water. Swirl gently; wait 30 minutes before use, etc."

Versus

"Follow designated control procedures."

The detailed QC directions in the above example are **superfluous** and add virtually nothing in terms of useful information for a laboratory-oriented and trained analyst. Stick to the essentials and important information when editing your PM. CMS (CLIA) discusses in section §493.1251 of the Survey Procedures and Interpretive

4: Method Validation and Verification

Overview

A quick introduction

Method Verification of performance is a "collective term which refers to a series of exercises that the laboratory undertakes to ensure and document that a method is working properly (at minimum, it meets manufacturer claims)" before placing the method into routine use. The process entails performing experiments, collecting data, calculating statistics, and making judgments on those statistics.

Calibration is "setting the device/system so that it yields correct results." The process of setting your watch to the correct time (if you remember watches that needed this activity), or of initially adjusting the bathroom scale to zero, is a calibration. Calibration implies that changes or adjustments are or can be made, although many devices are now "factory-" calibrated and cannot be changed by the lab.

Calibration Verification is the process of checking (without changes or adjustments) the "correctness" of the calibration. In the wristwatch analogy, confirming its time against the "correct" time of an atomic clock is equivalent to calibration verification. With CLIA, this process also defines the reportable range of test results or the range of values (low to high) known to be accurate and precise. The CAP coined the term "analytical measurement range (AMR)," which includes the reportable range.

In the clinical laboratory...

Currently CLIA and accreditation requirements range from rigorous protocols to no verification at all. The supposedly simple, waived tests like "dipsticks" used in the physician's office laboratory require no method verification. For FDA-approved nonwaived (moderate and high complexity) methods, laboratories must verify the achievement of manufacturer claims. For FDA-approved tests that are modified and Laboratory-Developed Tests (i.e. home-brewed and not FDA-cleared or approved), laboratories at this time must establish

the performance specifications and determine other pertinent performance characteristics such as calibration and QC. This section walks you through the validation and verification process and identifies what needs to be done according to CLIA and the different accrediting agencies.

Waived tests

CMS (for CLIA), COLA, The Joint Commission and CAP have **NO** specific method verification, calibration or calibration verification requirements for waived testing other than to follow, at a minimum, the manufacturer instructions.

Nonwaived (CLIA Moderate & High Complexity) Tests

In the original roll-out of CLIA regulations, in the 1992 Federal Register, the government delayed implementation of validation requirements for moderate complexity testing to accommodate newly regulated laboratories, many of whom would not have the necessary resources.

Things changed in 2003 when CMS published the "final" CLIA regulations, which combined the quality requirements – method verification, calibration and/or calibration verification – for FDA-approved moderate and high complexity testing into one set of **nonwaived** testing requirements. As long as test sites follow manufacturer directions, the same testing requirements apply except for the more stringent personnel requirements for high complexity methodologies. When a test site (1) modifies manufacturer directions (even with waived methods); or (2) uses "in-house" Laboratory-Developed Tests (LDTs, which are not FDA-approved), the test site must ***establish* all** performance specifications (§493.1253(b)(2) and determine calibration and control procedures (§493.1253(b)(3).

Beginning April 24, 2003

Under CLIA, test sites introducing a nonwaived method into their laboratory must go through the performance specification verification process. For **unmodified FDA-cleared systems** (§493.1253(b)(1)),

5: Quality Control
(According to the CLIA Requirements)

Overview

QC and waived test methods.

For laboratories inspected for CLIA compliance, **waived tests are exempt** from mandated QC requirements, although test sites must meet all manufacturer-specified and/or recommended QC requirements. Test sites performing waived methodologies also are expected to follow the manufacturer directions and apply good laboratory practices. CAP, TJC and COLA have specific QC requirements for all test complexities, including those in the CLIA waived classification (see Chapter 10: Point of Care Testing).

Note: Provider-Performed Microscopy, consisting of specified tests performed by physicians, nurse-practitioners, physician assistants, etc., as part of a patient's medical examination, is a subset of moderately complex (nonwaived) testing. QC is required "whenever possible."

QC and nonwaived test methods.

The original CLIA regulations (1992) broke new ground by mandating **daily** QC for all moderate and high complexity tests. The 2003 CLIA regulations combined these two complexity categories into the **nonwaived** category and both now follow the same CLIA quality control requirements identified in §493.1256. CLIA states that QC must monitor the **complete analytical process** including environmental conditions, the test system and the operator. Section §493.1256 also emphasizes that QC needs to monitor the accuracy and precision for *immediate error detection* and facilitate detection of errors *over time*.

Note: While not explicitly mentioned, CLIA implies that QC requirements are achieved through analysis of **external liquid controls**. All other QC approaches fall under Section §493.1256(d) Laboratories (particularly POCT) wanting to use other QC approaches must develop **Individualized Quality Control Plans (IQCPs).** (See Chapter 6.)

On April 2016, the definition of acceptable control material changed. CMS issued a memo stating that acceptable control materials now include on-board (inside the testing device) ampules/cartridges provided they have matrices similar to patient specimens and follow all elements of the analytic process (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-20.pdf). As a result, laboratories may decide after evaluating their testing device(s), that an Individualized Quality Control Plan (IQCP) is not even necessary.

Follow manufacturer directions.

This is the basic premise of CLIA and all other accrediting agencies. If the manufacturer has specific QC requirements, the laboratory must follow these, at a minimum.

Note: Failure to follow manufacturer directions moves waived, PPM, and moderately complex methodologies into the **high complexity** category. This requires all methods to meet nonwaived QC requirements and the high complexity personnel requirements, and establish all performance specifications (§493.1253(b)(2)).

In general, two controls per day is the minimum QC frequency.

However, the laboratory director must determine whether or not this minimum requirement is *sufficient* to ensure quality to meet the needs of the patients. Manufacturers may require *more* QC for some methodologies and some specialties and analytes, i.e., for blood gas, more controls or more frequent controls are required. (See sections §493.1261 – §493.1278.)

CLIA §493.1256(d)

Section §493.1256(d) accommodates new technology that integrates QC/QA functions (electronic/procedural/built-in internal controls) to automatically (without operator intervention) assess some elements of test quality. This technology is typically used at the point of care. Under CLIA regulations, test sites can use alternative QC to meet CLIA's requirements, provided the site develops and follows a director-approved **Individualized Quality Control Plan (IQCP)**.

IQCPs are discussed in Chapter 6. In this chapter we focus on "traditional" QC.

CLIA QC Requirements for Nonwaived Testing

CMS in CLIA's Section §493.1256 outlines the specifics:

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process.

(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in §493.1253(b)(3).

(c) The control procedures must –

(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual[SOM] that provides equivalent quality testing, the laboratory must—

Perform control procedures as defined [above] unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.

Microbiology (Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology) §§493.1261 -.1265
Routine chemistry (Blood gas analyses) §493.1267
Hematology (Manual cell counts; manual, nonmanual coagulation) §493.1269
Immunohematology §493.1271
Histopathogy §493.1273
Cytology §493.1274

6: Individualized Quality Control Plans (IQCPs)

IQCP became an official new CLIA QC option (section §493.1256(d)) on January 1st, 2016. Sites (primarily at POC) that develop IQCPs for their nonwaived devices and unique testing situations still meet CLIA QC requirements *without* analyzing daily external liquid QC. Unlike traditional external QC that focuses primarily on the analytical phase of testing, IQCPs formalize what test sites do *throughout* the testing process to ensure quality test results.

IQCP is voluntary. Test sites that do not want to develop an IQCP will need to perform external QC for each analyte on days that patient testing is performed, regardless of the test device's built-in quality assessments.

The Backstory of IQCP (QC questions, unaddressed & unanswered)

When CLIA began in 1992, labs assessed the quality of test results by analyzing daily at least two (and sometimes 3) levels of external, liquid QC materials (§493.1256). In the mid-1990s, point-of-care (near-patient, bedside) testing arrived. Many of these small, self-contained, handheld instruments included "built-in" manufacturer quality assessments – electronic function checks, procedural controls, etc. While CMS did not initially agree with these alternative assessment approaches, they did not require sites to perform additional daily external QC. Instead, CMS stated that "future" CLIA revisions would address the issue.

In 2003, CMS addressed the "built-in quality assessment" issue by adding an "equivalent quality (control) option" that allowed labs to rely on the testing devices' built-in qualify assessments in lieu of daily external QC. This option was controversial from the beginning. Few laboratories seemed to understand the meaning of "equivalent quality testing" or the "equivalent quality control" (EQC) concept. In 2005,the former director of CLIA even admitted at a CLSI/CMS

Forum, "We blew it," in response to EQC concerns. The EQC option era lasted from 2003 through 2015. 2016 brought in IQCP era.

The Birth of IQCP (the path from EQC to EP23 to IQCP)

Almost immediately after EQC implementation in 2003, CMS faced criticism particularly for EQC's lack of a strong scientific basis. To overcome concerns, CMS encouraged CLSI to develop guidelines -- one for manufacturers to describe the capabilities of their alternative assessment approaches and one for laboratories to facilitate appropriate QC selection. Unfortunately, the CLSI manufacturer guideline was ultimately abandoned. The second guideline was released in October 2011. CLSI EP 23, *Laboratory Quality Control based on Risk Management*, describes how laboratories can use risk management concepts to customize QC activities based on testing technology and mitigation of risks (errors) throughout the entire testing process. The CMS IQCP option is based on risk management. Those labs choosing to rely on a test device's built-in quality assessment to meet CLIA's daily QC requirements must follow an IQCP they specifically developed for a testing device and testing situation.

Note: Just to be clear, EP 23 is a voluntary guideline. Labs may find this guideline helpful in meeting CMS IQCP requirements.

You either volunteer to develop an IQCP that justifies your reduced QC frequency, or you volunteer to increase your QC to run every day.

Should Test Sites Adopt IQCPs?

IQCPs are applicable for all nonwaived testing performed in all CLIA specialties and subspecialties *except Pathology*. Accrediting organizations also accept the QC option, but there may be some differences and/or limitations. Make sure to check with your agency. When deciding if the option is for you, help is offered in CMS' brochure – *Individualized Quality Control Plan, Conditions to Consider when developing an IQCP* (https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliabrochure12.pdf). You should also consider additional factors, including test system capabilities and

vulnerabilities; CLIA requirements, extent and volume of POCT, external QC costs, and staffing levels and competency.

Note: Perhaps the main reason to develop an IQCP is to avoid analyzing 2 (in some cases, 3) daily levels of external controls for each analyte tested. An exception is for those sites choosing instruments meeting CMS' *expanded definition* of acceptable QC materials. Instruments that have built-in liquid controls that evaluate the entire analytical pathway and have matrices sufficiently similar to real patient samples *do not need* IQCPs.

Note: CMS mandates IQCP development be conducted by "in-house" personnel using "in-house" information. The thought is that each IQCP is unique because every testing situation is unique. However, staff **can** and **should** use the many development tools available from CMS, manufacturers, professional organizations, etc. The IQCP must be unique, but the information used within an IQCP doesn't have to be created from whole cloth.

Risk Management

IQCPs are based on **Risk Management (RM)**, a systematic process of identifying, assessing, and controlling potential errors throughout the entire testing process. This is not a new concept to labs. A common RM activity of modifying processes to eliminate identified recurring errors is a common practice. Below are terms associated with RM.

- **Risk** is the chance that an "error" will cause harm or loss/ adverse outcome to a patient. Risk is estimated from the probability of the error occurring and the severity of the harm or loss to the patient when the error occurs.
- **Risk Assessment (RA)** is the fundamental process of identifying and evaluating potential failures and errors that could occur in the pre-analytical, analytical, and post-analytical phases of the testing process.
- **Risk Mitigation** describes the elimination, reduction, or detection of identified risks (errors). For those risks identified, but NOT mitigated (eliminated), the test site must assess the impact or significance of each. The goal of IQCP is to report only acceptable quality test results.

7: Quality (Assurance) Assessment

Introduction

In the CLIA 2003 update and the accompanying *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* (Appendix C in the SOM), the term "quality assurance" became "quality assessment," with requirements integrated into the entire testing process – pre-analytical, analytical and post-analytical. CMS also suggested that the progression to Quality Assessment is an evolutionary change, which improves and aligns the regulations with current practices in competent laboratories.

Historically, the concept of Quality Assurance is tied closely to the theories of Total Quality Management, Risk Management and Quality Management Systems, which now permeate laboratory activities worldwide. The Joint Commission, CAP, and COLA formally include these concepts in their laboratory inspection process as well.

Quality Assessment

Curiously, while CMS seems to mandate a ***"Quality Management Systems (QMS) Approach"*** for all segments of clinical laboratory operations, QMS is never, in the extensive SOM or CLIA regulations, defined. Nevertheless, CMS (CLIA) includes under laboratory directors' responsibilities (§ 493.1407;1447): ensuring that QC and QA programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The closest to a definition is in the introduction (§493.1200), where CMS gives three key components (from its viewpoint) of a quality management systems approach:

Subpart K – Quality Systems for Nonwaived Testing

§493.1200 Introduction

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor quality systems for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) Each of the laboratory's quality systems must include an assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality systems are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

Let's extract some of the key ideas:

a) Develop a quality system **appropriate for your particular laboratory** that covers the pre-analytic, post-analytic and analytic phases of testing.

b) On an ongoing basis, select Quality Indicators to check on the system to ensure the integrity of the total testing process.

c) Evaluate data collected from Quality Indicators to identify, evaluate and resolve problems.

d) Implement, when necessary, processes for continuous quality improvement.

e) Document all activities.

COLA in its 2024 Laboratory Accreditation Manual clearly describes the why and what of quality assessment is so important to ensure quality patient results:

…A QA program helps standardize testing…evaluates each "process" in the laboratory…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.

CAP's 2024 Laboratory General Checklist (GEN.13806) requires a laboratory to have a document describing its overall QMS. CAP defines QMS as a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services. CAP's QMS, modeled after ISO 15189 and CLSI documents, includes QA

activities for monitoring key indicators of quality (GEN.20316) in the pre-analytic, analytic, and post-analytic phases of the testing process.

The Poor Lab's View of Quality Assessment

The CLIA regulations through the various sections outline the components of a Quality Laboratory System: Certification, Proficiency Testing, Facilities and Administration, Quality Control and Calibration, Personnel and Inspection. By inference – Meet these requirements and you have in place a Quality System! Now continuously monitor all aspects of the entire system – collect data, evaluate, resolve (if necessary), improve and document. That's QA – Quality Assessment.

The CLIA regulations take great pains to emphasize "the entire system" – the pre-analytical, analytical and post-analytical aspects of the testing process.

Quality Assessment – General Guidance

CLIA applies QA requirements to nonwaived testing only. CAP, The Joint Commission, and COLA, apply QA concepts to *all* testing, regardless of test complexity.

For CLIA, whether a laboratory is offering (nonwaived) blood gas testing, running a transfusion service, or is a complete cytogenetic reference laboratory, the following requirements relating to QA apply: (§§493.)

- .1230 Monitor and evaluate the overall quality of the system and correct deficiencies
- .1231 Maintain patient confidentiality
- .1232 Specimen identification and integrity
- .1233 Complaint investigations
- .1234 Communications – lab and person ordering tests and/or receiving results
- .1235 Competency Assessment
- .1236 Evaluation of Proficiency Testing Performance
- .1240 Monitor and evaluate the overall quality of the preanalytical systems and correct…

8: Personnel

MAJOR Personnel Qualification Changes - December 2023 Final Rule (Implemented December 2024) AND June 23, 2025 Memo (Implemented June 23, 2025)

Two CMS memos affect personnel qualification. In December of 2023, CMS published: Final Rule- Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-F). These CLIA personnel changes like all personnel and CLIA requirements establish the minimum. Accreditation agencies, states, and some specialty/subspecialty areas of testing may have more stringent requirements. The December 23 Final Rule (implemented on December 28, 2024) personnel changes for moderate and high complexity testing are incorporated in the current Federal Register (cFR) available on the CDC website. When reading the cFR make sure to pay attention to the **ANDs** and the **ORs**.

The 2023 Final Rule – ironically – is *not* the final story. On June 23, 2025, just 6 months after implementation of the Final Rule, CMS released a new memo (Memo # QSO-25-21-CLIA): Clinical Laboratory Improvement Amendment (CLIA) Enforcement Discretion and Clarification on Personnel Regulations. This new CMS memo responses to complaints concerning some personnel requirements "being too burdensome" in the December 2023 Final Rule. The June 23rd, 2025 memo shown below impacts moderate and high complexity Laboratory Directors and Clinical Consultants, and for the specialty of dermatopathology, Technical Supervisors. At the time of this PLG publication, the June 2025 changes are NOT included in the cFR. All changes impacting personnel are discussed and the current qualifications for the 9 CLIA mandated positions are incorporated into the personnel qualification forms outlined in this chapter and available for download in the Poor Lab's Extras section of the Westgard website.

Laboratory Director Qualifications (qualifications can differ for some specialty/subspecialty testing areas, accreditation agencies and states)

Note: Each CLIA requirement is associated with a specific cFR numbers, e.g., §493.14. As you will soon see, some of the cFR requirements are **negated** by the June 23rd, 2025 memo.

Licensed doctors of medicine and osteopathy (§493.1405(b)(1))/ §493.1443(b)(1)) qualifying through the pathologist track (anatomic or clinical or both) must be board-certified in clinical or anatomic pathology or both. Just being board eligible no longer qualifies.

For physicians (doctors of medicine, osteopathy, or podiatry) NOT board-certified (§493.1405(b)(2)). To qualify as a moderate complexity Laboratory Director, the physicians must have at least one year of experience directing or supervising nonwaived testing and at least 20 medical education/continuing educations credits/units covering clinical laboratory director responsibilities. Doctor of veterinary medicine (DVM) no longer qualifies.

Changes due to June 2025 memo (see "A" below): these individuals now have a choice – EITHER at least 1 year of experience directing or supervising nonwaived laboratory testing or 20 CE credit hours.

For physicians (doctors of medicine, osteopathy, or podiatry) NOT board-certified (§493.1443(b)(2)). To qualify as a high complexity Laboratory Director, physicians must have at least two years of experience directing or supervising nonwaived testing and at least 20 medical education/continuing educations credits/units covering clinical laboratory director responsibilities. Doctors of veterinary medicine (DVM) no longer are eligible.

Changes due to June 2025 memo (see "B" below): 20 CE credit hours are no longer required. Clarification "F" also applies.

Doctoral degree for moderate and high complexity Laboratory Directors (§493.1405(3)/§493.1443(3)(i)). This route now includes an earned doctoral degree in clinical or medical laboratory science or medical technology from an accredited institution. Additional requirements include at least 20 CE credit hours in laboratory practice and director responsibilities,

certification by an HHS approved board, and at least 1 year of experience (moderate complexity) directing or supervising nonwaived testing or 2 years for high complexity testing

Changes due to June 2025 memo (see "B" below): 20 CE credit hours are no longer required. Clarification "E" and "F" also apply.

Moderate complexity Laboratory Directors qualified with an appropriate master's (§493.1405(b)(4)) or bachelor's degree (§493.1405(b)(5)).

Changes due to June 2025 memo (see "B" below): 20 CE credit hours are no longer required. Clarification "E" is for Laboratory Directors qualified under (§493.1405(b)(4)).

Clinical Consultant Qualifications (§493.1417-.1419/§493.1455-1457). Non-pathologist physicians and doctoral scientists need 20 CE credit hours covering laboratory practices and director responsibilities plus 2 years of training or experiences or both for high complexity testing or 1 year (moderate complexity testing).

Changes due to June 2025 memo (see "C" below): 20 CE credit hours are no longer required for individuals previously qualified (before December 28, 2024) as Clinical Consultants.

The CMS June 23, 2025 memo impacts Laboratory Directors and Clinical Consultants. The changes described in items "A" – "F" became effective on release of the memo.

(A) CMS will allow laboratory directors qualifying under §493.1405(b)(2) to have either at least 1 year of experience directing or supervising nonwaived laboratory testing OR 20 Continuing Education (CE) credit hours in laboratory director responsibilities.

(B) CMS will not require the additional 20 CE credit hours currently required under §§493.1405(b)(3)(ii), 493.1405(b)(4)(iv), 493.1405(b)(5)(iv), 493.1443(b)(2)(iii), and 493.1443(b)(3)(iv).

(C) … any individual previously qualified as a clinical consultant will be able to continue to qualify without taking an additional 20 CE credits;

9:Preparing for Inspection

Keep your laboratory inspection ready!

CLIA mandates in Subpart Q that all test sites performing nonwaived testing undergo an inspection every two years. CMS or state agencies inspect laboratories for CLIA compliance. Professional accrediting organizations have their own inspectors/surveyors or use practicing laboratory professionals to assess compliance. All inspections are unannounced (but normally conducted within a known time frame). All have a similar focus. And all inspections need to take place while the test site's CLIA certificate is valid.

Certainly being "inspection ready" makes good sense. While readiness can't guarantee a stress-free inspection, it should make the process less of a hassle and, hopefully, the preparation will impress the inspector. First impressions count! Make sure that all of the inspecting agency's requirements are met and the proof (documentation) to show compliance is understandable and readily available for the inspector's review. In preparing, take full advantage of your agency's "get inspection ready/self-assessment" tools so that problems are found and corrected *before* the actual inspection. CMS and all the accrediting organizations want test sites to be ready and to successfully pass inspections.

Laboratories being inspected for CLIA compliance need to make sure to review the testing mandates (the regulations identified in §493.) in the Federal Register. *The Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Service* serves as a companion to CLIA and further explains CLIA while giving labs clues as to what inspectors will look for to determine compliance. For every CLIA requirement, these *Interpretive Guidelines* clarify the requirements, so laboratories know what is needed. They provide probes for inspectors to use in determining compliance. All CLIA requirements are associated with a "D" or deficiency tag. When a laboratory is found to be non-compliant with a particular requirement, the inspector cites the "D tag" rather than repeating the specific requirement.

Hints: Be Inspection-Ready; Be Ready to Successfully Pass Inspection

- Regulatory compliance is a MUST! Know and comply with your inspecting agency's requirements.
- Be aware of your agency's top deficiencies. Competency assessment, incomplete procedure manuals, proficiency testing enrollment and alternate assessments seem to top the lists year after year. Don't get caught in the same traps.
- Be prepared – leadership saves the day. Find problems before inspectors do. Be proactive and look carefully at all the laboratory's practices and procedures; don't assume all is fine. Self-inspection is important, so "do" what surveyors "do" before the actual mandated inspection.
- Make sure activities are consistently monitored; have a QA plan and a continuous quality improvement philosophy.
- Look good! Keep food/drink out of lab, have "no food"/"no flammables" signs on refrigerator doors, understand hazardous chemical labels, unclutter and clean workspace, practice safety first.
- Keep all staff in the loop. Prepare staff for potential inspector questions.
- Plan for the big event. Follow your inspection agency's policies and use suggested materials. Obviously, each agency disseminates what it thinks is important. CAP, TJC, and COLA tips are all slightly different but very helpful!
- Have documentation ready for the following and more:
    - Personnel qualifications and associated records
    - Up to date and complete procedure manuals
    - Training and timely competency assessments and records
    - Proficiency testing – from enrollment (at least for all regulated analytes) to reviewing of results, to applying/documenting corrective actions, to maintaining records
    - Method comparisons

- Calibration verification
- Equipment maintenance and associated documentation

The **Mock Inspection** (Section 9.1), as part of inspection readiness, is applicable to all agencies (CLIA, The Joint Commission, CAP, COLA, etc.). It is a general tool designed to assist sites *to begin* to prepare for and gather the appropriate information to successfully meet the inspector. You may want to start with this general checklist before using your accreditation organization's specific inspection tools. Highlights include:

1. Documenting general test site information
2. Quality assurance plans, monitors, method comparisons, accuracy assessments
3. Essential personnel records including documented training and competency assessments
4. Procedure manual requirements, including policies and procedures
5. Quality Control Plan, QC evaluation, documentation, and corrective actions when needed
6. Proficiency testing – enrollment, performance, review
7. Reagent, QC, calibrator storage
8. Patient test results – critical values, documentation, audit trail that links everything together
9. Safety issues – biological, fire, electrical, disaster plan
10. Instrument maintenance
11. Instrument performance evaluation – accuracy, precision, reportable range, reference range (for nonwaived, FDA-approved, unmodified testing)) and also sensitivity, specificity, and other relevant characteristics for modified, FDA-approved testing and/or laboratory-developed testing (LDT).

10:Point-of-Care Testing

All POCT is Regulated by CLIA

All testing, regardless of where performed, is regulated by CLIA. CLIA regulates *every* testing site examining "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease..." In short, *all* testing sites are subject, at a minimum, to CLIA's testing regulations.

CLIA Certificates

All POCT must be done under an appropriate CLIA certificate. Information on applying for a CLIA certificate is discussed in Chapter 1 and available on the CLIA website. POCT conducted in most organizations fits into one of two broad scenarios: 1) the central laboratory holds a single CLIA certificate that covers all testing, including POCT, or 2) one or more POCT sites within the institution have separate CLIA certificates. There is no one right way; the choice is organizational and most often depends on who wants to be in charge, cost and administrative concerns.

Each certificate has a fee schedule, which is dependent upon test volume, number of specialties, and test complexity. CLIA regulations divide test methods into three categories: waived, moderate and high complexity. CLIA'03 combined moderate and high complexity into a single, **nonwaived** category with essentially the same testing requirements. Typically, POCT sites perform only *waived and nonwaived* (moderately complex) testing. Under CLIA and the other accrediting agencies, the *waived and nonwaived* categories have **different** regulatory requirements in terms of personnel, QC, performance verification, proficiency testing, etc. These will be discussed in detail.

Note: While most POCT uses waived methods, if a site develops its own test procedure or chooses to ***modify*** an existing FDA-approved procedure, the test automatically becomes **high complexity**. Modifications include not following the manufacturer's directions and/or performing the test on a sample or from an age group,

e.g., pleural fluid, serum, etc., not specified in the manufacturer's labeling. As a result, the modified method now is subject to *all* of CLIA's more stringent nonwaived (high complexity) personnel and performance specification requirements mandated for modified, FDA-approved tests and/or Laboratory-Developed Tests.

Note: In 2014, the FDA published draft guidelines for glucose meters used to test "critically ill" patients (see section 10.4). Most currently-used POCT meters are not FDA-approved for this patient population. Consequently, testing critically ill patients with these glucose meters is considered a modification ("off-label") use and automatically makes the device highly complex, and subject to the high complexity performance and personnel qualifications. Test sites can continue to use these meters, but must develop and follow a policy that defines critically ill and how to test these patients with an "approved" method (typically POC sends specimen to the central laboratory). Otherwise, for POC to continue to test critically ill patients, sites need to perform appropriate validation studies or implement a FDA-meter approved for this population. As of 2025, very few methods were officially cleared by the FDA for use with "critically ill" patients.

In other words, ***never*** modify a POCT method unless you are prepared to meet much more demanding regulatory requirements. See section 10.4 at the end.

Overview of CLIA Regulations for POCT Testing

When POCT is under the lab's certificate, the lab is responsible for the overall quality of testing and establishing a Total Quality Management (TQM) relationship among all test sites including the central laboratory. While the POCT sites must adhere to the appropriate CLIA regulations, the central laboratory generally is the primary focus of the inspection and is ultimately responsible for POCT oversight and test quality.

When the POCT site has its own CLIA certificate, CMS views the site as an independent lab responsible for meeting all regulations. It inspects accordingly.

10.1 Waived Methods (as of 2025)

Bacteriology/ Virology/ Parasitology

Chlamydia
N. Gonorrhoeae Streptococcus, Group A Influenza A & B
Aerobic/Anaerobic Organisms – Vaginal
Respiratory Viruses & SARS-COV-2
Adenovirus
Sialidase Activity – Vaginal Trichomonas
Respiratory bacterial pathogens
Yeast (Candida only)

Endocrinology Urine Pregnancy Test/HCG

Ovulation Test (Visual Color Comparison) Urine HCG
Collagen Type 1 crosslink, N-telopeptides FSH
LH
Estrone-3 Glucuronide Semen
TSH
Fern test, saliva Pregnanediol glucuronide

General Chemistry/ Miscellaneous

Amines Lactate
Cholesterol (Total, HDL, LDL) Triglycerides
Occult Blood - Fecal & Gastric
Fructosamine
Glucose Monitoring Devices Qualitative dipstick glucose (blood and urine)
Glycated hemoglobin, HbA1c Ketones (blood and urine)
pH (multiple fluids)
AMS, ALP, ALT, GGT, CK, LD BNP
Uric acid Creatinine
Blood urea nitrogen/ urea Calcium, total and ionized Protein, total Albumin
Bilirubin, total
Carbon dioxide, sodium, potassium, chloride Phosphorus
Lead HbA1c
Osmolality, tears

Hematology

Sedimentation Rate
Hematocrit
Hemoglobin
Prothrombin Time (PT)
Platelet aggregation
Platelet count
WBC count/differential
RBC count
Neutrophil percentage

General Immunology

H. Pylori Ab
Influenza A/B
B.Burgdorferi Ab (Lyme's)
Syphilis Ab
Herpes Simplex I and II Ab
Infectious Mononucleosis
Bladder Tumor Assoc. Ag
Resp. Syncytial Virus Ag
HIV Ab
HIV-1 and -2 Ag/Ab
Hepatitis C Ab
Matrix Metalloproteinases-9
Immunoglobulins

Toxicology

Nicotine and metabolites
Ethanol /Saliva Alcohol
Buprenorphine
Cocaine Metabolites
Cannabinoids
Opiates/Tramadol
Phencyclidine
Amphetamines
MDMA
Methamphetamines

Methylenedioxy-methamphetamine
Oxycodone
Barbiturates
Benzodiazepines
Methadone /EDDP
Tricyclic antidepressants
Blood lead
Morphine
Propoxyphene
Marijuana
Lithium
MMP-9
Nortriptyline
Fentanyl/Norfentanyl
Cotinine

Urinalysis

Catalase
Qualitative Dipstick/table tests
Microalbumin
Creatinine
Qualitative dipstick

Section 10.2: Comparison of Waived Testing Requirements

Requirement	CMS (CLIA)	COLA (2024) Accreditation	TJC Accreditation (2025)	CAP Accreditation (2024)
CLIA certificate	Yes, based on complexity level of test performed	Same as for CLIA	Same as for CLIA	Same as for CLIA
General requirements for test methods	Follow manufacturers' directions	Yes, also follow WAV standards in current Accreditation Manual	Yes, also follow WT standards in current Comprehensive Laboratory Accreditation Manual for Laboratory and POCT	Yes, also follow applicable standards in current GEN, COM, DRA, and POC Checklists
Quality control	Follow manufacturers' directions	Yes, also follow WAV standards in current Accreditation Manual	Yes, also follow WT standards in current Comprehensive Accreditation Manual for Laboratory and POCT	Yes, also follow applicable standards in current GEN, COM, and POC Checklists
Develop IQCP	No	No	No	No
Mandated personnel training/ competency assessment and documentation	No	Yes, documented training for each test authorized to perform and competence assessed and documented, semi-annually during the first year of employment and annually thereafter	Yes, documented training for each test authorized to perform and competency assessment at least at orientation and annually thereafter	Yes, documented training for each test authorized to perform and competency assessment at least at orientation and annually thereafter
Validation of method's performance	No	No, unless required by manufacturer or organization	No, unless required by manufacturer or organization	No, unless required by manufacturer or organization
Policies and procedures (standard operating procedures [SOP])	No (good laboratory practice requires documentation in patient record)	Yes, results are entered into patient record accompanied by pertinent information for interpretation	Yes, documented in the clinical record and quantitative results accompanied by reference interval	Yes, retained in permanent medical record and accompanied, when applicable, by reference intervals or interpretive ranges
Test result records	No (good laboratory practice requires documentation in patient record)	Yes, results are entered into patient record accompanied by pertinent information for interpretation	Yes, documented in the clinical record and quantitative results accompanied by reference interval	Yes, retained in permanent medical record and accompanied, when applicable, by reference intervals or interpretive ranges
Proficiency testing	No	No	No	Yes, if available; when not available, perform alternative accuracy assessment (check with CAP for updates)
Inspection	No, unless complaint is received or fraud suspected	Yes, for compliance to the WAV standards	Yes, for compliance to the 5 WT standards	Yes, for compliance to the appropriate GEN, COM, DRA, and POC checklist items

Section 10.3: Comparison of non-Waived Testing Requirements

Requirement	CMS (CLIA)	COLA Accreditation (2024)	TJC Accreditation (2025)	CAP Accreditation (2024)
CLIA certificate	Yes, based on complexity level of test performed	Same as for CLIA	Same as for CLIA	Same as for CLIA
General requirements for test methods	Follow manufacturer's directions; have policies and procedures in place for the pre-analytical, analytical and post-analytical phases of testing	Same as for CLIA	Same as for CLIA	Same as for CLIA
Procedure Manual (standard operating procedures [SOP])	Written policies and procedures, as appropriate from patient preparation to reporting (§493.1251) Approved by director initially and with any changes	Same as for CLIA Approved by director initially and with any changes; reapproved at least every 2 years	Same as for CLIA; approved by director initially and with any changes; reapproved at least every 2 years	Same as for CLIA; approved by director initially and with any changes; reapproved at least every 2-years
Quality Control	Follow section §493.1256 for general requirements and §§493.1261, .1267, .1269 and .1254 for analyte specific requirements; General QC requirement: 2 QC levels/test/day	Follow, as applicable, general QC section and test specialty requirements in current COLA Laboratory Accreditation Criteria manual	Follow, as applicable, general QC & test specialty standards in current Comprehensive Accreditation Manual for Laboratory & POCT	Follow, as applicable, QC and test specialty standards in current POC and COM Checklists
IQCP to replace daily QC	Yes, follow 493.1256(d) in Interpretive Guidelines and latest CMS directiveson acceptable control material	Yes, following QC 31 - and latest CMS directives on acceptable control material	Yes, following QSA 02.04.01 and latest CMS directives on acceptable control material	Yes, following QC requirements and latest CMS directives on acceptable control material
Proficiency testing in a CMS-approved PT program when PT is not performed for a nonwaived analyte, and accuracy assessment (493.1236(c)) must be made every 6 months.	Yes, follow, as appropriate §§493.801-865 for "regulated" analytes; when PT is not	Essentially the same as for CLIA, but follow COLA standards (PT 1 –PT 18)	Essentiallythe same as for CLIA; followTJC standards	Yes, following COM.01300 - .01950

Requirement	CMS (CLIA)	COLA Accreditation (2024)	TJC Accreditation (2025)	CAP Accreditation (2024)
Personnel qualifications	Follow §§493.1403 - .1425	Same as for CLIA	Same as for CLIA	Same as for CLIA; see DRA checklist for more detail
Testing personnel training and on-going competency assessment	Yes, qualified (education/experience) technical consultant (or director) is responsible for identifying (initial) training needs and ongoing (twice the first year and at least annually thereafter) competency assessments (§493.1403(7)(8))	Same as for CLIA	Same as for CLIA	Same as for CLIA
Initial method verification at start-up (for unmodified, FDA-approved methods)	Follow §493.1253 (accuracy, precision, reportable range, and identify reference range)	Same as for CLIA	Same as for CLIA	Same as for CLIA
Ongoing assessment of reportable range (every 6 months);	Yes, §493.1255(b)(3) (accomplished through calibration verification)	Same as for CLIA	Same as for CLIA	Same as for CLIA (CAP in POC checklist terms this analytical measurement range (AMR)
Method correlations (at least every 6 months)	Between all methods under same CLIA certificate (§493.1281)	Same as for CLIA	Same as for CLIA	Same as for CLIA

10.4 On the use of glucose meters on the "critically ill"

Blood glucose meters (BGM) have become an essential tool in healthcare delivery. Clinicians and patients rely on the quick and easily generated BGM results with little thought on possible issues with the measurement. This changed back in March 2010 when the FDA held a public meeting to respond to the accumulating evidence that BGM measurements are not perfect. The meeting was the start of FDA's several year quest to resolve issues with BGM accuracy and off label use. The FDA's final version – Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use – is for BGM manufacturers not laboratories or users. Although users are impacted by these FDA regulations. The FDA regulations are available at:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use

FDA's document focuses on BGM accuracy due to the expanded use of meters in a variety of settings and with multiple patient populations, including "critically ill" patients. Except for one model, the BGMs used today are intended to monitor glucose levels in diabetic patients, not critically ill patients. Each manufacturer in its product insert identifies the BGM's intended use and limitations. Using any test outside FDA-approval for intended use is considered "off-label" and changes the test complexity from waived to high complexity, having more stringent CLIA requirements including personnel and performance specification validation.

You can imagine the outcry of laboratories, to be told, in effect retroactively, that they have been using BGMs off-label on the critically ill. This is definitely a case of the FDA closing the barn door once the horse is already out. In defense of the FDA position, they are entirely correct that the waived clearance process used for most of today's meters only evaluated performance on more stable patient populations never the critically ill. But, no one had been enforcing this interpretation of the regulation. Another point to be made about these new requirements: they are meant to be aimed at manufacturers, not at laboratories and hospitals. The goal is to

make manufacturers improve the performance of glucose meters and submit more detailed evaluations of the devices on critically ill patients. Therefore, in the future, when the FDA approves glucose meters for waived status, more will be known, and more confidence can be assumed in the use of these devices. However, in the short term, hospitals and laboratories who are stuck with the devices they have, which are not cleared for the critically ill must carry on and adjust their practices. If sites wish to continue to use the devices on the critically ill, an off label application, they are required to perform extensive validation studies and make sure the testing personnel meet high complexity testing requirements. Laboratories rightly feel that they have gotten stuck in an impossible situation. They are being punished *retroactively* for failures not of their own doing.

Note that in 2014, most likely as a response to FDA's early edicts, Nova Biomedical completed the validation studies on its StatStrip Glucose Hospital Meter System to reaffirm its waived status and achieve clearance for testing critically ill patients. Its FDA clearance allows, "specifically [the meter's] use in all types of hospital patients, including critically- ill patients." Nova initially received BGM waived clearance for non-critically ill patients back in 2006. The 2014 clearance announcement included a description of what is considered critically ill and the extent of the studies necessary to gain clearance:

"Today's clearance is for indications that include using arterial or venous whole blood from patients in all areas of a hospital with various conditions, including: trauma, cancer, sepsis and infection; cardiac, kidney, neurological, obstetric, gynecological, gastroenterological, endocrine, and lung issues; and people recovering from general or cardiothoracic surgery. "Data supporting this clearance included a study of more than 1,650 patients with a range of medical conditions, taking various medications, and being treated in a variety of hospital departments, such as cardiac, emergency intensive care, and surgical. Results showed agreement in blood glucose results compared to a comparator laboratory glucose analyzer in all patient types tested."

https://www.accessdata.fda.gov/cdrh_docs/reviews/K181043.pdf

In updating this PLG, we searched for other BGMs having FDA critically ill clearance. We identified none! If you can, let us know. The lack of BGMs with this clearance shows that there has been no rush of manufacturers seeking this clearance, which requires substantial effort. The FDA requirements mandate that for each critically ill patient segment, the manufacturer must submit a study consisting of at least 50 appropriate samples, a daunting number even for manufacturers. Adding the more stringent FDA performance (accuracy) requirements to the mix increases the regulatory burden of applying for BGM waived status and may further deter manufacturers to seek FDA approval. This, of course, limits labs future BGM choices.

Perhaps in response to the limitations of BGM, more and more effort is being put into the use of continuous glucose meters (CGMs) and devices that are implanted or attached to the patient. The convenience of the CGM, which frequently requires no painful self-pricking, makes this new option popular and, perhaps, will cause BGM to eventually go out of favor.

How to avoid inspection problems with your current BGM?

In the meantime, how do those hospitals and laboratories "stuck" with BGMs not FDA-approved for critically ill testing proceed without encountering inspection problems? The first word of advice - don't tempt the inspector. Be inspection ready by knowing your BGM's intended use and limitations and have a policy for identifying critically ill patients. Secondly, know your options for testing and compliance. For those we offer the following suggestions and recommendations from CMS and Dr. James Nichols:

1. CMS recommendations - "Options for CLIA Compliance for Waived Blood Glucose Monitoring Systems"

   https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-11.pdf

   - Continue to use a BGM as a waived device by adhering to manufacturer's instructions, or,

- Labs with a Certificate of Waiver can choose to use a BGM off-label (e.g., testing critically ill patients when meter is not FDA approved to do so), IF they:
- Obtain a Certificate of Compliance or Certificate of Accreditation;
- Establish the performance specifications for the critically ill population tested; and meet additional CLIA high-complexity testing and applicable State regulations, or,
- Choose to change to a BGM without any critically ill patient population limitations in the manufacturer's instructions, or,
- Submit blood glucose specimens from patients identified as critically ill to a CLIA-certified/accredited laboratory for testing.

2. Dr. James Nichols, Professor of Pathology, Microbiology, and Immunology, Medical Director of Clinical Chemistry and POCT, and Medical Director of Special Testing at Vanderbilt University Medical Center, presented testing suggestions in CAP Today's article – Devices, Decisions: POC glucose in the critically ill.

   https://www.captodayonline.com/devices-decisions-poc-glucose-critically-ill/

   - Define criteria to identify patients as critically ill. Then develop and have staff follow your identification policy. Dr. Nichol's laboratory defines 'critically ill' as any of the limitations in the manufacturer's package insert.
   - Switch to a meter cleared for use in critically ill patients, e.g. Nova Biomedical's StatStrip, Note that capillary samples" are not acceptable for testing the critically ill.
   - Stop using BGMs with all patients defined as critically ill . Instead use an alternative method such as a blood gas analyzer or send the sample to the laboratory for analysis.
   - Use the BGM off-label and comply with CLIA's high complexity requirements.

The Poor Lab's Advice for Labs using BGM non-FDA-approved for critically ill patients:

The Poor Lab's view is that while this set of FDA regulatory changes was not executed well, in the long run, labs and patients will be better off. This is yet another situation where labs are at the mercy of the manufacturers. If we don't demand that manufacturers do better and take more responsibility, we'll end up having to handle the residual risks.

In the meantime, those labs using non-FDA-approved (for critically ill) BGMs need to decide how to proceed without incurring inspector citations. Know your meter's intended use and limitations and decide how it will be used – adhere to manufacturer requirements or use off label. In the future, we hope all BGM entering the market will have FDA approval for the critically ill. This approval should be a routine, standard feature for all BGMs. But for now, it's a waiting game. One approach for some laboratories is to develop a policy that simply states that glucoses on "critically ill" patients will be tested in the central laboratory by conventional instrumentation. For those labs that want to continue to test critically ill patients, they need to bite the bullet and treat their meters as high complexity devices and meet CLIA's high complexity requirements.

Index

Q

R

S

T

V

W