

# U.S. quality assurance regulations for decentralized testing

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In the U.S. all testing, including decentralized testing, is regulated according to the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88). Congress passed CLIA'88 to ensure accurate, reliable, and timely test results regardless of test site.

These quality control, quality assurance, and proficiency testing requirements are found in a series of Federal Register announcements and continue to evolve in response to changes in the testing environment.

## All laboratory testing including decentralized testing is regulated

In the U.S. all testing, including decentralized testing, is regulated according to the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) [1, 2]. Congress passed CLIA'88 to ensure accurate, reliable and timely tests results regardless of test site.

These requirements along with a series of announcements continue to evolve in response to changes in the testing environment and can be found in the codified edition of the Federal Register on the Centers for Disease Control and Prevention website [3].

Three federal agencies, the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) develop the specific requirements for testing sites to meet CLIA'88.

All are based on test method complexity or difficulty to perform the testing, i.e., the more complicated the test, the more stringent the requirements. Three major test complexity categories for laboratory methodologies have been established - waived, moderate, and high complexity.

Most testing performed in decentralized sites is classified as waived or moderately complex.

The specific classification for a methodology is available on the CMS website [4]. For the 50 plus “simple and fool-proof” waived tests, the only requirement under CLIA is to follow the test manufacturer’s directions. pH, blood gases and electrolytes are classified as moderately complex.

The minimum quality standards for moderately complex tests include mandates for personnel, quality control, quality assurance, proficiency testing (external quality assurance), and patient test management (requirements to maintain sample integrity and patient identification throughout the testing process) [2, 3, 5-9].

The test site must be aware that once any waived or moderately complex test methodology is modified, the test automatically becomes highly complex and is subject to CLIA’s most stringent performance standards.

### To follow CLIA’88?

While all testing sites must meet the minimum CLIA requirements, not all sites directly follow CLIA. Several professional accrediting organizations having testing performance standards that meet or exceed those of CLIA have been “deemed” or approved by CMS.

When a testing site chooses to be accredited by one of these organizations and, through inspection, demonstrates compliance with the standards, the site, in essence, is meeting the CLIA requirements.

The primary deemed organizations include: (1) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), (2) the Laboratory Accreditation Program of the College of American Pathologists (LAP-CAP), and (3) COLA (formerly known as the Commission of Office Laboratory Accreditation) [10-12].

JCAHO accredits entire healthcare organizations and the decentralized test sites within the organization must meet, at a minimum, JCAHO requirements for testing.

JCAHO does accept CAP and COLA inspections for sites performing moderate and high complexity tests. JCAHO, however, does not accept CMS (for CLIA) inspections.

LAP-CAP inspects decentralized testing when it is under the direction of the central laboratory or when the site specifically seeks CAP accreditation. LAP-CAP does not accept JCAHO, CMS or COLA inspections. Testing sites seeking COLA accreditation are located primarily in physician offices and small hospitals. COLA will accept JCAHO inspections.

### Which regulations to follow?

Usually decentralized testing sites have some latitude in choosing the regulations to follow. It is important to realize that the central laboratory and the decentralized sites within the same institution may be accredited by different organizations.

To further complicate the picture, some states may impose additional requirements. The final determination is in large part the consequence of a series of institutional decisions based on who (the director) is responsible for decentralized testing. It is dependent on whether the decentralized testing site is under the central laboratory’s CLIA certificate or has its own [9-14]. It also is influenced by the type of accreditation (i.e., JCAHO) sought by the institution as a whole.

### Who holds the CLIA’88 certificate?

All testing must be done under an appropriate CLIA’88 certificate. Currently there are about 170,000 registered testing sites and 97,000 of these are associated with physician offices (**Table 1**) [4].

Testing in most hospitals fits into one of two situations: (1) the central laboratory holds a single CLIA’88 certificate which covers all the hospital’s testing, including decentralized testing, or (2) decentralized testing sites have one or more separate CLIA certificates.

When decentralized sites are the central laboratory’s responsibility, the director of the central laboratory is

	TOTAL LABS	TOTAL POLs
Total laboratories registered	173.191	
Total labs registered in non-exempt states	167.744	96.922 (56 %)
Moderate & high complexity testing*	22.056 (13 %)	14.715 (15 %)
Waived**	91.516 (55 %)	44.111 (46 %)
Provider Performed Microscopy***	37.455 (22 %)	31.376 (32 %)
Accreditation****	16.717 (10 %)	6.720 (7 %)
<p>* testing sites inspected by CMS for compliance with CLIA regulations.  ** testing sites perform only the simple, waived tests and are not inspected by CMS  *** a group of 9 tests performed by clinicians as part of their practice of medicine.  **** testing sites inspected by government approved accrediting organizations (COLA, JCAHO, CAP, etc.)</p>		

TABLE I: CLIA Enrollment by Certificate Type (October 2001) - Source: CMS website: <http://www.cms.gov/clia/statupda.pdf>

responsible for the overall quality of all testing and must ...ensure that testing systems developed and used for each of the tests ... provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing... [and]... ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur [2, 3].

When a decentralized site has its own CLIA'88 certificate, the site is viewed and inspected as an independent laboratory. The site's director is responsible for meeting all the regulations and assuring its overall quality.

Many hospitals having multiple testing sites establish a decentralized testing committee to help provide oversight and ensure that the right decisions are made for quality and effective testing that benefit the patient, staff and healthcare organization.

## Overview of testing requirements - CLIA'88, COLA, JCAHO and CAP

### CLIA'88 and COLA requirements

CMS bases its inspection on the CLIA'88 regulations. COLA's requirements parallel CLIA's. COLA places a great deal of importance on education. Each site completes a written checklist as part of a self-inspection and this same checklist is used for the on-site inspection [15].

CLIA and COLA have no specific requirements for waived testing other than to follow the manufacturer's directions.

### Quality control (QC)

The requirements for QC of moderate complexity testing are, perhaps, the most confusing. They include mandates for daily QC, procedure manuals, calibration, remedial action for out of control situations and documentation.

Specifically, decentralized testing sites must adhere only to sections §493.1201 and §493.1202c of the Federal Register (as shown in **Table II**) as well as QC practices identified for specific testing areas such as blood gases (§493.1245) and hematology and coagulation (§493.1252) [2, 3].

Under CLIA and COLA, electronic controls can fulfill the daily QC requirement in place of traditional liquid controls provided the manufacturer specifies their use. However, whether liquid or electronic controls are used, the testing site must include, at a minimum, the appropriate number and levels of controls.

The results must be documented and reviewed to ensure the adequacy of the testing process. Documentation of both the QC results and the specific remedial action to "out of control results" must be available to the inspector.

## CLIA's Minimum QC Requirements

- following manufacturers' directions;
- having a procedure manual that identifies how to perform the tests and report results;
- performing and documenting calibration procedures or checking calibration at least once every six months;
- assaying at least two levels of control material each day of testing (a run cannot exceed 24 hours) and keeping records;
- performing and documenting any applicable specialty and subspecialty control procedures
- blood gases require, at a minimum, one control sample every 8 hours of testing and a calibrator or control in each run unless the instrument is calibrated at least every 30 minutes,
- automated hematology and coagulation test systems require two levels of controls every 8 hours of testing and each time a change in reagent occurs;
- performing and documenting remedial actions;
- maintaining records of all quality control activities for two years.

TABLE II

Decentralized sites may choose to impose more, but not less, stringent QC requirements on the testing process. It is the director's responsibility to establish appropriate standards for quality including QC limits and practices.

JCAHO inspects decentralized sites using its most recent, standards identified in their Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services [10].

## Verification of performance specifications

CLIA and COLA, for moderately complex tests, allow the decentralized site to rely on the manufacturer's performance data for sensitivity, specificity, and reportable range, and to use the manufacturer's cited reference range, if it is suitable for the testing site's clientele.

The site must verify the accuracy of each test at least twice each year through some mechanism such as proficiency testing, split-patient samples, or assaying products with known values. Good laboratory practice would dictate that the site verify that the method's accuracy and precision can meet the needs of the testing site's clientele before placing the method into routine use.

## Joint commission on accreditation of healthcare organizations (JCAHO) requirements

## QC

Like CLIA, JCAHO mandates two levels of QC per test per day for most analytes, daily review of the QC results, etc. For pH/blood gases, JCAHO requires, at a minimum, three levels of QC every 24 hours with at least one level analyzed every 8 hours of testing. Decentralized sites that test for only 8 hours still must run the three levels during the hours of operation.

The general JCAHO QC requirements for moderate complexity include: (QC.1) each specialty and subspecialty (of testing) has a documented QC program; (QC.1.2) the QC system includes the validation of methods used; (QC.1.3) the testing site's QC system includes daily surveillance of results by appropriate personnel; (QC.1.4) the testing site takes remedial action for deficiencies identified through QC measures or authorized inspections and documents such actions; (QC.1.5) the site ensures that QC results meet its criteria for acceptability before it reports patient test results; and (QC.1.6) the laboratory follows written guidelines

for the proper preparation, storage, dispensing, and periodic evaluation of all reagents, including water, to provide for accuracy and precision.

JCAHO also accepts electronic controls to fulfill the daily QC requirements. However, JCAHO requires that the reliability of these controls be verified (usually through parallel analysis of liquid controls) before they are placed into routine use and that external (usually liquid) controls are run periodically to validate that no change in the method's performance is occurring with the test system.

### Verification test method performance specifications

JCAHO wants to see "some evidence" that all test methods/instruments can meet the needs of the site's clientele. This includes data on accuracy and precision, data that verifies the reportable range for each analyte, and confirmation (by the site's director) that the reference ranges are appropriate for the testing site's clientele. However, this information only needs to be collected once for each method or instrument model.

As part of the JCAHO total quality management philosophy, performance history, including QC data, can be used as the "evidence" of adequate performance when a method used in one location is instituted in another.

### College of American pathologists' laboratory accreditation program (LAP-CAP)

CAP accredited sites must follow the LABORATORY GENERAL CHECKLIST (GEN) plus one of the three special Checklists that specifically address testing outside of the central laboratory: (1) POINT-OF-CARE TESTING CHECKLIST (POC), (2) LIMITED SERVICES LABORATORY CHECKLIST (LSV) for a limited menu of tests, or (3) BLOOD GAS LABORATORY CHECKLIST (BGL), which is testing blood gases and related whole blood analytes at sites that are medically and/or administratively separate from the central laboratory. [11-18]

CAP's philosophy is that all clinical laboratory tests must meet the same performance standards regardless of the CLIA test complexity classification.

### QC

CAP also requires two levels of QC every 24 hours for most analytes, such as electrolytes, and two levels of controls every 8 hours of testing and each time a change in reagent occurs for automated hematology and coagulation. For pH and blood gases, CAP requires two levels of controls every 8 hours of testing (POC.0550, LSV.41650, BGL.27350).

CAP also requires all decentralized test results to be recorded in a permanent record and be accompanied by appropriate reference ranges.

CAP allows electronic controls to fulfill the daily QC requirement for unmodified test systems cleared by the FDA and classified by CLIA as either waived or moderate complexity as long as these are a "scientifically acceptable alternative...that controls the entire analytic process" (POC, LSV and BGL "Controls" Section).

The testing sites must have data to validate the reliability of these controls before placing them into routine use. CAP also mandates periodic evaluation of the stability of the test system with liquid controls. In all cases, the appropriate number and levels of controls must be included and the control results documented and reviewed to ensure the adequacy of the testing process.

### Verification test method performance specifications

The Laboratory General Checklist (GEN) includes performance verification requirements - accuracy, precision, sensitivity, specificity, reportable range and reference range - for each test procedure. Specificity implies an evaluation of the method's ability to respond correctly in the presence of interfering substances.

CAP allows a testing site to rely on reagent/instrument manufacturers' data to establish specificity (GEN:42030)

and permits the use of literature references or manufacturer's product information for the reference range as long as the ranges are appropriate for the testing site (GEN:40946).

For all analytes, CAP requires testing sites to establish and reverify every 6 months the analytical measurement range, or reportable range, i.e., the range of values that the site accepts as being accurate (GEN:40944). Technically, values outside the range should not be reported unless they can be verified, for example, on another instrument.

## General requirements for all accrediting organizations

### Proficiency Testing (PT)

Successful participation in PT is a requirement for CMS (CLIA), COLA, JCAHO, and CAP. CLIA, COLA and JCAHO only require PT for the "regulated" analytes. These analytes include -- pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, and tHb - as well as others [4]. CAP requires PT participation for all analytes, when available, tested (GEN:10000).

When the central laboratory is responsible for decentralized testing, it usually participates in PT through a CMS-approved program (see CMS website for listing). The decentralized sites interface with the PT process at least semi-annually through mandated method comparisons with the central laboratory under the quality assurance requirements.

When the decentralized site holds its own CLIA certificate, the site must participate in PT through a CMS-approved program.

### Quality Assurance (QA)

All accrediting organizations emphasize QA and continuous quality improvement. The decentralized sites must have their own QA plan or be part of the central laboratory's QA plan, which addresses the ten categories identified in **Table III** [2, 3].

### CLIA's Quality Assurance Requirements

- Patient test management (§493.1703)\*
- QC (§493.1705)
- PT (§493.1707)
- Test comparisons (§493.1709)
- Relate results to clinical data (§493.1711)
- Personnel (§493.1713)
- Communi-cations (§493.1715)
- Complaints (§493.1717)
- Staff review (§493.1719)
- Records (§493.1721)

\*The numbers are specific sections of the CLIA'88 regulations.2,3

TABLE III

Most critical for a decentralized site under the central laboratory's CLIA certificate is the mandate that test results from different instruments be compared at least twice each year. This links the results from the decentralized site to those produced in the central laboratory and ensures that different methods/instruments generate comparable (in the opinion of the director) results. JCAHO takes this comparison a step further.

JCAHO only wants to see one consistent level of care throughout the entire accredited institution. Consequently, JCAHO extends this semi-annual, correlation requirement across the entire institution regardless of the CLIA certificate arrangement.

If patients within a JCAHO accredited institution have the potential of having the same test done at multiple test sites (e.g., physician office, emergency room, central laboratory, intensive care, bedside), test results between the sites must be compared and documented at least every six months. In addition, all accrediting organizations want continued assurance that the methods/instruments used provide accurate results.

For those analytes not evaluated by PT, some other mechanism must be in place to establish, on a semi-annual basis, the accuracy of the analyte.

Requirement	CMS (CLIA)	COLA	JCAHO	CAP
QC (most analytes - 2 levels/day)	Yes	Yes	Yes	Yes
QC (pH/blood gases)	1 control/8 hours (and 1 control or calibrator each run)	1 control/8 hours (and 1 control or calibrator each run)	1 control/8 hours (and 1 control or calibrator each run) 3 levels of control must be run over 24 hours	2 controls/8 hours of testing (and 1 control or calibrator each run)
QC (tHb - 2 levels/8 hours)	Yes	Yes	Yes	Yes
Accepts electronic controls	Yes	Yes	Yes, with verification of reliability and periodic assessment with liquid controls	Yes, with verification of reliability and periodic assessment with liquid controls
Method verification before implementation	No, accepts manufacturer's data	No, accepts manufacturer's data	Accuracy, precision, reportable range and appropriateness of reference ranges	Accuracy, precision, reportable range and appropriateness of reference ranges
Assessment of reportable range (every 6 months)	No	No	No	Yes
Participation in regulatory proficiency testing	CLIA regulated analytes only (pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , tHb, etc.)	CLIA regulated analytes only (pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , tHb, etc.)	CLIA regulated analytes only (pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , tHb, etc.)	For all analytes tested, when available
Method correlations as part of quality assurance	Within same CLIA certificate	Within same CLIA certificate	Across entire healthcare organization	Within same CLIA certificate
Establishment of accuracy (twice each year) for analytes not in proficiency testing	Yes	Yes	Yes	Yes
Personnel training and annual competency assessment	Yes	Yes	Yes	Yes

TABLE IV: Comparison of Selected Testing Requirements by Organization

## Summary

CLIA'88 is synonymous with the implementation of uniform quality standards for all testing sites in the US. Decentralized testing sites in hospitals usually choose to meet the quality requirements of government "deemed" professional organizations, primarily - JCAHO, CAP and COLA. **Table 4** compares selected test requirements.

The unique nature of decentralized testing (instruments, circumstances, personnel, etc.) must be considered

when attempting to comply with testing regulations. The site's director must take an active roll in establishing and maintaining quality.

Aside from complying with the basic quality mandates, an additional concern relates to education, since non-laboratory personnel often perform testing. Test sites must be engaged in a defined program for training testing personnel and assessing competency on an ongoing basis to ensure quality.



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