# Regulatory Compliance for Point-of-Care Testing: 2009 United States Perspective

Sharon S. Ehrmeyer, PhD, MT(ASCP)[a,*], Ronald H. Laessig, PhD[b]

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- Clinical Laboratory Improvement Amendments
- Point-of-care testing compliance • Regulatory compliance
- Testing requirements • Professional accreditation

All clinical laboratory testing in the United States, regardless of where performed, is regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88 or CLIA) and overseen by the Centers for Medicare and Medicaid Services (CMS).[1] The current CLIA regulatory requirements are specified in the January 24, 2003, ''Final Rule.''[2] A companion document, *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services in the State Operations Manual* (published January 2004) further clarifies each requirement and identifies what activities CMS inspectors expect test sites to do to meet these requirements.[3]

CLIA profoundly changed the prevailing United States regulatory philosophy by imposing uniform requirements for all clinical laboratory testing regardless of where tests are performed. This ''site-neutral'' approach means that for any particular test (eg, a cardiac marker, blood glucose, or a urine dipstick), whether it is performed at a large reference laboratory, a major clinic, a local hospital, a small physician office laboratory, or at the patient's bedside, is subject to the same regulations. The clear intent of the ''site-neutral'' CLIA regulations is to ensure that all clinical laboratory testing meets a minimum standard of quality. Conceptually, all patients are entitled to quality laboratory results, regardless of where, when, or who performs the tests.

CLIA specifies minimum testing requirements for every site examining ''materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease…''[2] While CLIA sets the minimum requirements and CMS inspects sites for compliance, voluntary accreditation through

[a] Clinical Laboratory Science/Medical Technology Program, Department of Pathology and Laboratory Medicine, University of Wisconsin School of Medicine and Public Health, Madison, WI 53706, USA
[b] Department of Population Health Sciences, Wisconsin State Laboratory of Hygiene, University of Wisconsin School of Medicine and Public Health, Madison, WI 53706, USA
* Corresponding author.
*E-mail address:* ehrmeyer@wisc.edu (S.S. Ehrmeyer).

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professional organizations ''deemed'' by CMS to have equivalent or more stringent requirements than those specified in the CLIA is an alternative for point-of-care testing (POCT) sites. POCT sites in hospitals usually meet the CLIA requirements by being accredited and inspected by one of these professional organizations, primarily the Joint Commission, the Laboratory Accreditation Program of the College of American Pathologists (LAP-CAP), or Cola (formerly known as the Commission on Office Laboratory Accreditation).[4–6] Professional organizations charge a fee for inspection, assessment, and accreditation. When POCT sites meet the accrediting agency's requirements, as assessed through inspection every 2 years, the test site also meets the CLIA requirements. The CMS, however, has the right, for quality-assurance purposes, to reinspect up to 5% of testing sites accredited by CMS-deemed organizations. While each organization has a slightly different approach to conducting the inspection, the accreditation standards must be fully compliant with the CLIA regulations. Test sites have the option of selecting the accrediting organization. However, POCT sites must be cognizant of the basic CLIA requirements as well as all applicable professional accreditation standards, guidelines, or checklists.

## CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 CERTIFICATES

The first requirement for any POCT site is to perform testing under an appropriate and current CLIA certificate.[7] Some sites mistakenly think that no CLIA certificate is necessary when patients are not charged for the testing. This is not true. The holder of the CLIA certificate for a POCT site within a hospital typically fits into one of two broad scenarios: (1) the central laboratory holds a single CLIA certificate that covers all institutional testing, including POCT, or (2) POCT sites within the institution have their own, separate CLIA certificates. There is no one right way; the choice most often depends on policy, administrative concerns, and cost. Free-standing POCT sites, such as physician office laboratories, including those in multiphysician practices (clinics), must have their own CLIA certificates. CLIA certificates are based in part on the complexity of the methods. Complexity is determined by the technical difficulty and the knowledge, skills, and experience necessary to perform the testing. Because of personnel and quality requirements, usually only waived or moderate-complexity methods are used at the point of care. However, if a POCT site develops its own test procedure or chooses to modify an existing procedure approved by the Food and Drug Administration (FDA)—such as deviating from the manufacturer's directions—the method automatically falls into the high-complexity category and is subject to CLIA's most stringent requirements. The cost of CLIA certificates for independent test sites is determined by a CMS fee schedule, which is set according to test volume, specialty/subspecialty of testing, and test-complexity level.[8]

The FDA places each test method into one of three categories: waived, moderate complexity, and high complexity. However, in the 2003 regulations, the CMS combined many requirements relating to moderate- and high-complexity test methods and sometimes refers to these two categories as *nonwaived*. Primarily because of personnel and method-validation requirements, the waived category has the least stringent testing requirements while the high-complexity level has the most stringent. Moderate complexity includes the subcategory of provider-performed microscopy procedures (PPMP), which is designated specifically for physician and midlevel practitioner testing as part of their professional practice of medicine.[9] The limited test menu for this category consists of wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements; potassium hydroxide preparations; pinworm examinations; fern tests; postcoital direct qualitative examinations of vaginal or cervical