

*Special Commentary*

**The Cost of Maintaining Diagnostic Accuracy in Laboratory Testing**

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In the healthcare industry, there seems to be a nebulous notion regarding what a clinical laboratory actually is and does. Many seem to think it consists of a big black box where specimens are put in and results come out. The reality, however, is much more complex. An average hospital clinical laboratory consists of hundreds of trained staff working 24 hours a day, 365 days per year processing specimens, maintaining instruments and running quality checks, and performing manual, and highly specialized, diagnostic testing on every single type of specimen imaginable.

While laboratory medicine continues to evolve, one crucial aspect of operations has stayed consistent over time – the qualifications of laboratory personnel. However, as the shortage of healthcare personnel continues, the landscape of quality is changing. On April 1, 2016, CMS published guideline S&C: 16-18-CLIA, which is a revision of previous standards of the qualifications needed to perform laboratory testing. The guideline particularly states, “Bachelor’s and Associate’s degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.”<sup>1</sup>

While nursing staff is an indispensable part of the healthcare team, their education does not meet the biological science requirements to give nurses enough knowledge to perform moderate and high complexity laboratory testing to the standards to under the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88).

### **Testing Complexity<sup>2</sup>**

Laboratory testing is categorized into three main complexity levels: waived/low, moderate, and high. Under CLIA ’88, each category of testing requires different levels of training and education of the personnel performing the testing to ensure the quality and accuracy of the results.

Waived testing can be performed by anyone who has had documented training by the facility. Waived testing includes, but is not limited to, Point-of-Care testing such as fingerstick glucose and dipstick urinalysis. These tests operate on manufactured kits and instruments that do not require interpretation by the user beyond reading a result output or a color change.

Moderate complexity testing can only be performed by individuals who hold a certification in laboratory medicine after pursuing a Bachelor’s or Associate’s degree, and have documented proficiency and maintenance of certification. Examples of moderate complexity testing include complete blood counts chemistry panels, and urine microscopy which are performed on instruments that require daily documentation of quality control, and results may require interpretation by the laboratory professional. Some laboratory testing also can require manual performance; for example, much of the testing done before a transfusion is manually performed as the technology is still limited in what can be performed by automation.

High complexity testing can also only be performed by individuals who hold a certification in laboratory medicine after pursuing a Bachelor’s degree, with documented proficiency and maintenance of certification. This testing can include cytogenetic analysis and molecular testing. Certain categories of high complexity tests may even require further certifications in specific laboratory disciplines.

### **Educational Requirements for Laboratory Professionals<sup>3</sup>**

Under the current standards, there are two basic certifications for laboratory professionals that are required to perform diagnostic testing in clinics, hospitals, and reference laboratories, and each is tied to a specific educational track:

- MLS(ASCP) - Medical Laboratory Scientist certified by the American Society of Clinical Pathology, which is achieved after the completion of a Bachelor’s degree.
- MLT (ASCP) - Medical Laboratory Technician certified by the American Society of Clinical Pathology, which is achieved after the completion of an Associate’s degree.

The most direct way to obtain certification is by completing a Clinical Laboratory Science program accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). However, individuals outside of a NAACLS program who have a Bachelor's or Associate's in a biological science may also sit for the Board of Certification (BOC) after five years and three years of experience of working on the bench in the laboratory, respectively. The ASCP BOC has very precise guidelines for who is eligible to sit for the exam. Each application to take the test is thoroughly reviewed and approved before the applicant can have the ability to schedule the exam.

Additionally, to remain certified, individuals must complete the required credit hours and apply for recertification every three years. The credits must be dispersed across all laboratory disciplines, regardless of the individual's area of specialty. Those who also hold additional certifications for high complexity testing must do the maintenance of certification program for the standard MLS certification in addition to the education to maintain their specialty certification.

Competency is also assessed annually. While certification is maintained through educational courses, MLSs and MLTs are also tested on their technical ability to perform the testing on the bench. This is assessed through blind specimens from regulatory agencies or through specimens prepared by laboratory management. Each laboratory professional treats the blind specimen as a real patient sample, and is tested on accuracy and completeness. This process ensures that each person who is performing diagnostic testing has the knowledge and skills to perform the testing consistently and accurately.

#### **Educational Track Comparison<sup>4,5</sup>**

CMS's policy change, which deemed a nursing degree equivalent to a biological sciences degree, is quite problematic for the laboratory community because when the educational tracks are compared for laboratory professions and nurses, nurses take 20 fewer semesters of hard science disciplines compared to clinical laboratory scientists.

*Course comparisons adapted from curricula at Marquette University*

Required Course for the Board of Certification	Number of Semesters - CLS	Number of Semesters - RN
Chemistry (General, Organic, Biochemistry)	4	2
Biology	2	0
Statistics	1	0
Anatomy and Physiology	1	1
NAACLS Courses in Laboratory Disciplines	15	0

Both courses of study offer a comprehensive education. However, in comparison, students in a nursing curriculum complete one-third of the biological science courses and none of the laboratory discipline courses that are required by students in a clinical laboratory science curriculum. Additionally, nurses do not take the minimum required courses to sit for the MLS or MLT Board of Certification. Nursing education focuses on clinical care, and rightly so. However, they have little experience in the detailed science and technical skills required to perform laboratory testing with accuracy and precision.

Clinical Laboratory Science courses offer training in testing methodology, sample collection, quality control, and precision studies. Students are required to show mastery of all complex technical skills before entering a clinical rotation. After completing the didactic courses of the curriculum, students must rotate at a hospital or clinic for a minimum of six months, spending anywhere from 2 weeks to 8 weeks in a single laboratory discipline. At the end of each rotation, students sit for a capstone exam in that discipline that mirrors the format and level of comprehension required to pass the ASCP BOC. Successful completion of each clinical rotation and earning a passing grade on each capstone exam is required for a student to graduate from the program. Failure to show mastery of knowledge and competency of skills requires remediation in each discipline that was not passed. Most employers will often hire students before graduation and before passing the BOC because the rigorous nature of the program can be trusted to produce capable professionals. Failure of an employee to pass the BOC exam within one year of employment will result in immediate termination as the regulatory standards set forth by CLIA '88 will not tolerate uncertified individuals performing laboratory testing.

### **Quality of Waived Testing Performed by Non-laboratory Personnel<sup>6</sup>**

Under current testing complexity standards, nurses do perform waived testing such as rapid Streptococcus antigen testing, Point of Care measurements at the bedside, and urinalysis dipsticks. In a study performed by CMS and the CDC from 1997 to 2006, it was found that testing performed by nursing staff and laboratories managed by nursing professionals did not meet the minimum requirements of accuracy, precision, and quality stated in CLIA '88.

The study noted multiple deficiencies in the facilities surveyed:

- Using outdated instructions and procedure information
- Lack of quality control testing before testing patient samples
- Reporting incorrect terminology and/or units of measure
- Lack of adherence to expiration dates of the test system, reagents, and control materials
- Storing testing materials under improper conditions and temperatures
- Lack of performance of confirmatory testing when required
- Lack of performance of instrument calibration and function checks

The study findings were particularly worrisome because the CLIA requirement for performing waived testing is to follow the manufacturer instructions. Additionally, the study discovered that facilities were also performing tests of a higher complexity than the site was accredited to perform, and the quality measures for the more complex tests were not being followed.

More than seven billion laboratory tests are performed nationally each year. With an estimated 70% of medical decisions based off of laboratory results, it is crucial that the individuals performing testing are educated, certified, and competent. Adequate personnel are important not only for patient care, but also to eliminate as many redraws and repeat testing as possible, which can drive up costs. As reimbursement continues to move towards quality over quantity, providers need accurate, timely results to continue to provide high quality patient care. While to err is human, and errors can occur at any phase of the testing process, personnel trained in laboratory medicine are extremely cognizant of this. Laboratory professionals take the appropriate measures to reduce errors as much as possible by following protocols with no variation, performing quality control testing, and constantly monitoring specimen quality and the testing systems being used. Through the constant quality checks and documentation that quality has been verified, every laboratory is committed to ensuring patients do not experience adverse outcomes from a testing error.

Integrated healthcare teams continue to be the gold standards for medical practice. However, those teams can only operate most efficiently when the role and scope of practice of each provider is recognized and respected. A medical laboratory scientist would not be expected to take vital signs and administer vaccines; we simply have not been taught to do so. In reverse, nurses should not be allowed to perform moderate and high complexity testing without proper education and training. Allowing personnel to perform the job of another provider without ensuring competency will only lead to a reduction in quality and increase in cost of care.

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