Scope of Practice

Background

The current healthcare environment is one of considerable uncertainty, unprecedented change and limitless potential. The advances in medical research, genetics, and molecular methodologies, provide great opportunities for scientific and clinical advances in the detection, treatment and prevention of disease. Although there is great promise, the continuing changes in healthcare delivery and financing will have a profound impact on the availability and utilization of both new and existing diagnostic services.

The dynamic scientific, economic and regulatory environment has provided expanded roles for non-physician healthcare professionals, including medical laboratory scientists. This environment will allow the important issues of cost containment, access, quality, patient safety and appropriate utilization of laboratory services to be more effectively addressed. While the cost of healthcare continues to rise, there are significantly increased expectations from clinicians and healthcare consumers to deliver information in a manner that will facilitate rapid diagnosis and treatment.

At a time when the cost of healthcare is over 17% of the Gross Domestic Product (GDP), clinical laboratory services continue to provide a significant level of value.[1] Healthcare is being impacted by evidence-based medicine (EBM), evidence-based practice (EBP), and comparative effectiveness research (CER). Laboratory information provides significant data and scientific information that contribute to the development of EBM, EBP, and CER.[2] As healthcare becomes more evidenced based, and that evidence is provided by medical laboratory professionals, it is important that medical laboratory scientists assume their role as members of the interprofessional healthcare team. It is time for the appropriately qualified healthcare professionals to provide the most efficient and effective level of care by advancing independent and collaborative roles. Ultimately, by having each specific healthcare professional play their most appropriate role the total care provided to the consumer will be optimized. Appropriate utilization of healthcare resources through interaction and contributions of the interprofessional healthcare team can contribute to avoiding unnecessary invasive procedures, decrease cost, and improve patient safety. In today's complex delivery system, maximizing the effective delivery of all components of healthcare will help address the rapidly escalating cost, patient safety, and issues of access to quality and affordable healthcare.

The Medical Laboratory Science Profession

In previous statements of opinion, policy and positions, the American Society for Clinical Laboratory Science (ASCLS) has established that medical laboratory science is a profession: distinct from the practice of medicine; characterized by its own Body of Knowledge and Scope of Practice; which certifies its own practitioners; and requires of its practitioners competency in scientific, technical, managerial and scholarly principles, and high standards of performance and professional conduct.

ASCLS defines the profession of medical laboratory science as encompassing the design, performance, evaluation, reporting, interpreting, and clinical correlation of clinical laboratory testing, and the management of all aspects of these services. Clinical laboratory tests are utilized for the purpose of diagnosis, treatment, monitoring and prevention of disease. The profession includes generalists as well as individuals qualified in a number of specialized areas of expertise including microbiology, virology, hematology, immunology, transfusion medicine, clinical chemistry, endocrinology, toxicology, cytogenetics, and molecular diagnostics. Integral features of each of the specialties include diagnostic testing, research, consultation, education, information management, marketing and administration. ASCLS has a professional code of ethics that sets forth the principles and standards by which medical laboratory professionals practice.

Description of the Scope of Practice

Medical laboratory professionals, as members of the healthcare team, contribute to the prevention of disease, and the diagnosis, treatment, and prognosis of pathophysiological conditions in humans. Medical laboratory personnel are responsible for assuring reliable and accurate laboratory test results.

Downloaded from http://hwmaint.clsjournal.ascls.org/ on October 14 2026

Quality clinical laboratory testing is evidenced by: performing the correct test, on the right person, at the right time, producing accurate test results, with the best outcome, in the most cost-effective manner. This is accomplished by:

- Ensuring that appropriate clinical laboratory tests are ordered;
- Procuring clinical laboratory test samples in an efficient, timely manner;
- Producing accurate clinical laboratory test results;
- Correlating and interpreting clinical laboratory test data;
- Disseminating clinical laboratory test information to clinicians and patients in a timely manner;
- Evaluating the outcome of clinical laboratory testing for each individual patient and the entire health care system;
- Utilizing qualified medical laboratory personnel.

The practice of medical laboratory science requires:

- Assessing, designing, evaluating and implementing new clinical laboratory test methods;
- Evaluating the appropriateness of existing and new clinical laboratory methods for clinical utility, cost-effectiveness and cost-benefit analysis;
- Developing, implementing, and reporting results of clinical laboratory research;
- Designing and implementing cost-effective delivery models for clinical laboratories, including their services and personnel;
- Developing and implementing a comprehensive Quality Management System to include:
  - Quality control and assurance of clinical laboratory testing services;
  - Competency assessment of personnel;
  - Integration with other aspects of the healthcare delivery system for ensuring appropriate utilization of clinical laboratory testing services;
  - Continuous process improvement activities to effectively utilize human resources.
- Designing, implementing and evaluating academic curricula for the education of new medical laboratory professionals;
- Designing, implementing and evaluating academic curricula for advanced education of medical laboratory professionals;
- Designing, implementing and evaluating continued education activities and career growth opportunities for medical laboratory professionals;
- Promoting awareness and understanding of the use of the clinical laboratory.

Description of Current Practice

The following scenarios describe specific examples of the scope of practice of clinical laboratory science.

Providers of Clinical Laboratory Services

Medical laboratory scientists qualified by education and experience, perform laboratory tests and provide test results to clinicians and to consumers upon request or upon clinician referral. These services can be used to assess wellness and identify disease risk factors, as well as assisting in the diagnosis, monitoring and treatment of disease. Medical laboratory scientists exercise prudence and judgment to ensure that such services are consistent with good practice and sound professional ethics. In addition, medical laboratory scientists may own or operate laboratories.

Directors of Full-Service Clinical Laboratories

Medical laboratory scientists, with appropriate graduate education, can direct full-service clinical laboratories. This function is firmly grounded in (a) applicable state law, and (b) federal regulations governing clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 and laboratory participation in Medicare and Medicaid.

Consultants for Clinical Laboratory Services

Medical laboratory scientists may appropriately provide assistance and advice to clinicians, manufacturers, and consumers of clinical laboratory testing services about the:

- Design and service scope of clinical laboratories;
- Appropriate utilization, selection and sequencing of clinical laboratory tests;
- Clinical correlations and interpretations of the quality and utility of specific laboratory results in collaboration with clinicians;
- Design and development of clinical laboratory instruments, test kits and other components;
- Appropriate use, maintenance, quality assurance and other procedural and informational requirements.

Downloaded from http://hwmaint.clsjournal.ascls.org/ on October 14 2026

Levels of Practice

There are hierarchical levels of practice, based upon education and experience, for each of the three areas of medical laboratory science practice: scientific, managerial and educational. Specific knowledge and experience are required for each level of practice within the three areas. An individual is eligible to practice at various levels after acquiring additional experience, education, and demonstrating competence. Specific knowledge and experience is common to all three areas; none is mutually exclusive of the other. Demands of the health care environment often require an individual to practice in more than one area, thereby performing at different levels of practice.

The *scientific function* includes the production of test data, monitoring the accuracy, precision and utility of laboratory testing, the correlation and interpretation of test data, and the design, evaluation and implementation of new laboratory test methods.

The *managerial function* includes managing all aspects, technical, fiscal, workflow, and human resources, of laboratory operations.

The *educational function* includes the establishment and management of educational programs for new and current medical laboratory practitioners, other healthcare providers and consumers.

Qualifications for Practice

ASCLS believes that personnel standards should be prescribed for **ALL** personnel including directors, supervisors, medical laboratory scientists and other laboratory technical personnel to insure the accuracy and reliability of test performance. ASCLS supports the concept of the regulatory complexity model, and believes that personnel standards at the technical levels must be defined in terms of qualifications needed to perform testing at CLIA defined complexity levels.

- The individual qualified to perform CLIA waived tests must demonstrate competency, and would perform simple tests requiring little to no independent judgment and interpretation.
- The individual qualified to perform CLIA moderately complex tests must demonstrate competency as a medical laboratory technician and would perform, under direct supervision, more technically demanding tests with some degree of independent judgment and interpretation.
- The individual qualified to perform CLIA highly complex tests must demonstrate competency as a medical laboratory scientist, and would perform more technically complex tests requiring considerable amounts of independent judgment and interpretation.

ASCLS supports utilization of validated competency-based credentialing examinations for all laboratory practitioners performing moderate and high complexity testing. Waived testing should be performed by properly trained personnel. A certified medical laboratory scientist and or technician should conduct this training.

ASCLS supports the use of benchmarks to more succinctly typify positions at various levels of work and different types of work presently performed by practitioners in the clinical laboratory. A benchmark is defined as something that serves as the standard by which others may be measured.

- The benchmark for the medical laboratory scientist is the baccalaureate degree as awarded by a regionally accredited college/university including or in addition to successful completion of a medical laboratory science program accredited by an agency recognized by the U.S. Department of Education.
- The benchmark for the medical laboratory technician is the associate degree as awarded by a regionally accredited college/university including successful completion of a medical laboratory technician program accredited by an agency recognized by the U.S. Department of Education.
- The benchmark for personnel performing CLIA waived testing is successful completion of appropriate training for testing at this level. It is within the scope of practice of a certified medical laboratory scientist and/or technician to provide this training.

ASCLS supports the concept of equivalent routes for the medical laboratory scientist only in combination with a baccalaureate degree as defined by the Board of Certification (BOC).[3]

ASCLS supports the concept of equivalent routes for

Downloaded from http://hwmaint.clsjournal.ascls.org/ on October 14 2026

the medical laboratory technician only in combination with an associate degree as defined by the BOC.[3]

ASCLS supports the concept of equivalent routes for scientists in discipline specific areas of clinical laboratory science as defined by the BOC.[3]

Experience requirements for the medical laboratory scientist and technician equivalent routes incorporating full-time medical laboratory experience for equivalency must include **ALL** major disciplines typically required in the clinical component of a medical laboratory science education program accredited by an agency recognized by the U.S. Department of Education. If the credential is discipline specific, the clinical component must contain full-time experience in that discipline. Such experience shall be under the supervision of a certified medical laboratory scientist in a CLIA certified laboratory.

ASCLS supports the concept of career mobility (ladder) which includes utilization of validated competency-based credentialing examinations and documentation of continuing education to determine competency of personnel at all levels of responsibility.

ASCLS believes that all practitioners should demonstrate continued competence through recertification and/or documentation of continuing education as stated by the BOC.[3]

Summary

The current economic and regulatory healthcare climate benefits from the roles described for medical laboratory scientists and technician. These roles achieve high quality, cost-effective assessment, diagnosis, treatment, and prevention of disease to meet the needs of a changing healthcare environment.

References:

1. https://www.cms.gov/NationalHealthExpendData/25_NHE_Fact_sheet.asp
2. http://www.ahrq.gov/clinic/epcix.htm
3. Board of Certification –ASCP http://www.ascp.org/ Board-of-Certification/GetCertified

Downloaded from http://hwmaint.clsjournal.ascls.org/ on October 14 2026

This position paper was approved by the 2012 American Society for Clinical Laboratory Science House of Delegates.