

SCOPE OF PRACTICE

Board-Certified PhD Medical Laboratory Director

Purpose: This document describes for policymakers, healthcare administrators, and the public the qualifications and responsibilities of PhD Medical Laboratory Directors.

MEDICAL LABORATORY DIRECTOR

Medical Laboratory Directors (MLDs) are highly educated individuals with a doctoral degree (MD, DO, PhD, MD/PhD, or equivalent international degree), who typically work in a variety of settings, including health systems, teaching hospitals, and reference laboratories. Most MD or MD/PhD MLDs are pathologists by medical training, while PhD MLDs are board-certified and have formal training in one or more clinical specialties.

MLDs oversee all clinical, scientific, and/or operational aspects of the laboratory. They consult with other healthcare professionals (e.g., physicians, physician assistants, nurses, etc.) on issues of test utilization and interpretation and determine the optimum analytical methods to efficiently meet clinical needs and effectively reduce the cost of care. In the age of personalized medicine, MLDs apply their scientific knowledge to developing and delivering new laboratory tests to assist physicians in diagnostic and treatment decisions. MLDs provide a unique and critical perspective to the healthcare team.

MEDICAL LABORATORY DIRECTOR REQUIREMENTS

The Clinical Laboratory Improvement Amendments (CLIA) regulations specify that an MLD of a high-complexity laboratory must be either a Doctor of Medicine or Doctor of Osteopathy and meet certain certification or experience requirements, or have a doctoral degree in a chemical, physical, biological, or clinical laboratory science and be certified by a professional board approved by the Department of Health and Human Services. Board-certification is maintained through appropriate continuing education.

RESPONSIBILITIES

MLDs are responsible for the clinical and analytical evaluation of laboratory tests. They introduce, develop, validate, implement, and interpret laboratory tests that help physicians screen, monitor, and/or diagnose health disorders, assess wellbeing, and treat medical conditions. In addition, their duties may require direction of all laboratory operations, including compliance with laboratory best practices and regulations, and the investigation and resolution of test errors. In addition, many MLDs conduct research to advance the science of laboratory medicine and its contribution to patient care.

MLDs also advise physicians on the appropriate ordering of tests and interpretation of test results, including the clinical implications for patient management (e.g., recommending additional testing, writing interpretive notes for the medical record). MLDs are often called upon to share their expertise with fellow healthcare professionals and the public. Many MLDs teach and serve as mentors to the next generation of physicians, MLDs, and medical laboratory scientists. MLDs can serve as core teaching faculty for Accreditation Council for Graduate Medical Education-accredited pathology residency

programs and assess the clinical competencies of pathologists and MLDs in-training to ensure they achieve appropriate milestones within their specialty prior to graduation.

EDUCATION, TRAINING, AND CERTIFICATION

Doctoral Degree

A PhD MLD must have a doctoral degree in a chemical, physical, biological, or clinical laboratory science. The degree program, in addition to the requisite educational courses, should include:

- ▶ A thorough study of the scientific discipline in which the doctoral degree is awarded;
- ▶ Independent research that advances scientific knowledge; and
- ▶ A written and approved doctoral dissertation.

Some doctoral programs also require candidates to publish their research and teach/train new PhD candidates and laboratory technologists and technicians.

Fellowship

Prior to certification, doctoral scientists should participate in an accredited fellowship training program that prepares them for serving as an MLD. The program should emphasize:

- ▶ independent decision-making;
- ▶ training in different sections of the clinical laboratory and its subspecialties with the emphasis on the application of laboratory techniques to the diagnosis of human disease;
- ▶ interacting/communicating with and providing consultation to physicians and other healthcare providers;
- ▶ identifying and troubleshooting analytical problems that can impact clinical interpretation;
- ▶ developing and validating new tests;
- ▶ knowledge and application of business management principles;
- ▶ ensuring quality testing, in part through meeting quality metrics;
- ▶ ordering and interpreting tests;
- ▶ utilizing translational research;
- ▶ monitoring and assuring regulatory compliance;
- ▶ overseeing quality management/improvement efforts; and
- ▶ participating in scientific research and publishing/presenting the findings.

Fellowships may also include procuring grant support and applying for institutional review board approval.

Board Certification

A doctoral scientist serving as an MLD should have a broad knowledge of laboratory operations, analytical theory and processes, and an understanding of the pathophysiology of disease. Board certification is one of the most reliable means for ensuring a laboratory director meets these criteria. While experience and formal laboratory training are essential requirements for adequately directing a laboratory, they are not the only elements needed to direct a comprehensive laboratory.

Board certification ensures a standardized knowledge base and reflects a broad, deep, and up-to-date understanding of laboratory medicine, which permits MLDs to educate and guide other healthcare professionals, ensure the efficient use of resources, and maintain quality patient care and safety. In states that require clinical laboratory personnel to be licensed, certification by a recognized board is a requirement for licensure at the director level. Only individuals with doctoral degrees who meet certain education and training requirements and achieve specific professional experience can apply for board certification.

CORE COMPETENCIES

Professional Expertise

An MLD should possess an understanding of the scientific, regulatory, and business operations of the clinical laboratory that affect the delivery of patient care. Such an individual should be able to:

- ▶ develop and adapt testing to meet the needs of the patient population they serve;
- ▶ guide physicians in choosing the appropriate tests;
- ▶ interpret and communicate the test results;
- ▶ monitor and incorporate advances in laboratory medicine;
- ▶ ensure compliance with government regulations; and
- ▶ develop/oversee quality management plans and quality improvement processes.

One mechanism that can help the individual meet these duties is joining and becoming actively involved in professional associations, which can provide opportunities for promoting scientific advancement, obtain continuing education, and networking with colleagues.

Technical and Medical Knowledge

The MLD must also have a strong combination of technical and medical knowledge, including the ability to understand and apply biomedical concepts and processes to patient care. It is this combination of technical and medical knowledge that allows MLDs to make informed interpretations of the laboratory results that can help a physician assess, diagnose, and treat a patient. MLDs must also have a deep understanding of laboratory methods and their limitations to ensure the quality and accuracy of laboratory results.

Management and Communication Skills

An MLD should possess a wide range of skills to effectively perform their job. They must communicate to various audiences, orally and in writing, the interconnected information of laboratory medicine – ranging across scientific disciplines, analytical techniques, and information systems. Leading a laboratory also has administrative and operational components, thus MLDs should have strong organizational skills, including the ability to multi-task, delegate responsibilities, and effectively manage personnel.

Advancing Laboratory Medicine

Many MLDs conduct laboratory research, adapt existing devices to meet the needs of the patient, and collaborate and communicate with their partners in the diagnostics industry to improve and enhance laboratory technologies. This research may also involve identifying novel biomarkers that are vital to improving patient diagnosis and the management of care. In academic and commercial settings, these investigations typically involve clinical translational research to support independent or collaborative research in clinical trials or development of other medically relevant technologies. This research is often presented in peer-reviewed publications or at scientific conferences to disseminate it to others in the healthcare community. Increasingly, MLDs are applying data analytics techniques within the laboratory to improve efficiency and internal processes. They also are contributing invaluable expertise in applying laboratory data beyond the laboratory to clinical decision tools and public health programs.

Advancing Patient Care

MLDs play an important role in gathering and interpreting laboratory data, while also remaining up to date on advances in the field. In this capacity, they play a key role in improving patient care—both for the individual as well as for the broader healthcare community. Many MLDs are currently at the forefront of assessing and evaluating new technologies and approaches that meet emerging healthcare needs (e.g., molecular pathology testing, companion diagnostics, data analytics). These scientific and technological advances are resulting in many MLDs taking on a larger and more visible role in business and operational decisions.