

The Role of the Medical Laboratory Director

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The American Medical Association notes in its *Principles of Medical Ethics* that a physician “shall be dedicated to provide competent medical service with compassion and respect for human dignity.” As physicians whose profession involves the medical direction of pathology and clinical laboratory services, pathologists strive to provide high-quality, cost-effective services to support the needs of patient care. These services must be provided under the aegis of extensive legal and regulatory mandates of various governmental and nongovernmental entities, such as the Clinical Laboratories Improvement Amendments of 1988 (CLIA’88), College of American Pathologists (CAP), Joint Commission, US Food and Drug Administration, Centers for Disease Control and Prevention, as well as state and federal authorities. To accomplish his/her task, the pathologist can use tools of evidence-based medicine and clinical practice guidelines together with medical and scientific training and experience. At the same time, the Medical Director must be able to measure and demonstrate the value of his/her contribution in today’s competitive environment.

Fundamentally, the Medical Laboratory Director has three overlapping areas of responsibility: medical, educational, and administrative. The medical responsibilities center on the Medical Laboratory Director’s role in patient care as a physician health care provider. The educational responsibilities revolve around defining, establishing, and maintaining the scientific foundation of laboratory activities by education, research, investigation, and training. Finally, the administrative responsibilities focus on the day-to-day activities of a business operation, including legal matters, personnel,

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and communications and interactions within the laboratory and between the laboratory and the outside world.

Medical and clinical responsibilities

Medical responsibilities lie at the heart of the Medical Laboratory Director position. These matters are what make a Medical Laboratory Director different from any other kind of director. To an extent unmatched in any other profession, medicine and medical services directly affect the health, well-being, and livelihood of individuals and populations. What is logical and sensible from a purely financial perspective is not necessarily logical and sensible from the medical perspective. Inherent in this statement is a valuation on health and well-being. If a test result costs 10-fold more to provide at the point of care than in a core laboratory but with one tenth of the delay in receiving the answer, how does that match up against the added cost? Rightly or wrongly, decisions are routinely made that may make medical sense but not necessarily business sense from the pure commercial perspective of finance, strategy, or operation. The training required to become a physician provides the broad foundation necessary to provide the guidance and input for a medically rational business operation.

The Medical Laboratory Director is a physician who is qualified to make judgments about the medical significance of clinical laboratory data. He or she must be able to communicate effectively in interpreting laboratory data and relating correlations to referring physicians as appropriate. This responsibility includes understanding the underlying clinical science and the capability to “translate” those scientific facts to a direct care provider in a clinically relevant context. Pathology, in general, and the laboratory, in particular, sit at the interface of science and medicine, and the Medical Laboratory Director needs to be fluent in the languages of both disciplines. The Medical Laboratory Director provides consultations to physicians regarding the medical significance and interpretation of disparate laboratory findings, as well as appropriate and effective use of the laboratory. These medical consultations typically require privileges and credentialing at the facilities served. In keeping with the role as a provider of clinical services, the Medical Laboratory Director’s ethical responsibilities require that he or she promotes practices that are consistent with accepted ethical standards for the medical profession. As for any physician, the Medical Laboratory Director is expected to comply with the standard of care and applicable codes of ethics promulgated by licensure and regulatory agencies. In this way, the Medical Laboratory Director functions as a peer member of the medical community as he or she assists in the interpretation and correlation of laboratory data for patient management.

To meet these obligations, the Medical Laboratory Director must monitor all work performed in the laboratory to ascertain that reliable medical

data are being generated. Data must be aggregated and disseminated appropriately to providers capable of acting upon that information for diagnosis and patient management. This responsibility involves results emanating from the on-site laboratory as well as any data from specimens sent to reference laboratories. As such, the Medical Laboratory Director must select or at least approve of all referral laboratories, and the assurance of quality needed to make such a selection should be assessed for each test needed, similar to the analysis performed to support choice of an in-house testing platform. Major reference laboratories may have variable quality for testing performed in each subsection, and it is appropriate to ask for and receive performance characteristics and summaries of verification/validation data for every test sent out. In short, the Medical Laboratory Director ultimately is held responsible for medically useful, accurate information to be made available in a timely fashion to support the provision of accurate and reliable medical services to patients, regardless of whether the testing occurs on-site or is referred out to another laboratory.

The Medical Director can fill a different niche than the Laboratory Director, although they may be the same individual (the Medical Laboratory Director). The CAP Laboratory Accreditation application forms use the term "Administrative/Laboratory Director" distinct from the term "Laboratory/Medical Director." The Medical Director of the laboratory is a suitably qualified physician who is legally, morally, and ethically responsible for the scope, standards, and quality of service. He or she has the knowledge and skills in all areas of practice, which includes administration, education, research, and patient care. In contrast, the Laboratory Director is responsible for the overall operation and administration of the laboratory, including areas of personnel competency, equipment, safety, laboratory policies, quality assurance, proficiency testing, and reporting and delivery of results (see Code of Federal Regulations at 42 CFR 493.1407 and 493.1445) [1]. If the Medical Director and Laboratory Director responsibilities are separated and entrusted to two individuals, then clear and consistent communication between the two becomes critical. When this communication is not performed well, the results are painfully obvious.

CLIA'88 and the CAP require that the Laboratory Director meet one of three sets of conditions: currently licensed MD or DO (as required by the state where the laboratory is located) and board certified in anatomic or clinical pathology by the appropriate American Board; or currently licensed MD or DO (as required by the state where the laboratory is located) with at least 1 year of documented laboratory training during residency or at least 2 years of documented experience supervising high-complexity testing; or if a nonphysician, holds an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and maintains certification by a board approved by the Department of Health and Human Services (CAP Team Leader Assessment of Director & Quality Checklist item TLC.10100) [1,2]. In general, for all areas in which

the Laboratory Director is not qualified to direct any of the individual sections of the laboratory, the laboratory must retain the services of individuals who are qualified to direct those sections (TLC.10200) [2]. In short, the Laboratory Director must have sufficient responsibility and authority to implement and maintain the standards of the regulatory authorities (TLC.10300) [2].

The CAP Laboratory Accreditation Program has specific checklist questions regarding the Laboratory Director, all of which are phase II deficiencies if not met. Phase II deficiencies require a written plan of corrective action and supporting documentation as evidence of implementation of the plan. Failure to adequately correct a phase II deficiency can result in loss of accreditation. The Laboratory Director needs to fulfill the regulatory responsibilities outlined in CLIA'88 as well as meet the experience, educational, and training requirements and be available to the laboratory staff as needed. The Laboratory Director must ensure provision of appropriate anatomic pathology procedures (Checklist Question TLC.10600) [2] as well as consultations regarding the medical significance of laboratory data by physicians or doctoral scientists (TLC.10700) [2]. For anatomic pathology, in particular, a pathologist certified in anatomic pathology (or eligible to be certified) must perform such services or an appropriately qualified Consulting Pathologist must be retained. A close working relationship between the Laboratory Director and the Consulting Pathologist must be established, responsibilities delineated, and the on-site visits documented appropriately (TLC.11900, TLC.12100) [2]. The Consulting Pathologist serves as consultant to the medical staff for areas such as infection control, tissue review, death review, transfusion review, and quality management activities. (TLC.12000) [2]. As part of his/her designated responsibilities, the Consulting Pathologist may provide intraoperative surgical pathology consultations and advice on personnel matters, equipment purchases, quality control systems, safety, space requirements, and test delivery systems related to anatomic pathology (TLC.12300, TLC.12400) [2]. The frequency, duration, and depth of involvement of the Consulting Pathologist in the on-site laboratory activities must be considered adequate by the laboratory and medical staff (TLC.12200) [2]. At the discretion of the Laboratory Director, subspecialties of anatomic pathology may be provided by appropriately trained physicians who are certified in the subspecialty or who possess qualifications equivalent to those required for certification.

Educational responsibilities

Because the laboratory lies at the juxtaposition of medicine, science, and technology, the professional and technical workforce must maintain a level of technical understanding well beyond that of the average nonhealth care worker. This education extends beyond the initial training and orientation and must be continued as appropriate, because the underlying science and

technology advancements are continually incorporated into the working laboratory environment. The Medical Laboratory Director must ensure that there are sufficient personnel with adequate documented training and experience to meet the needs of the laboratory (TLC.11300) [2]. The Medical Laboratory Director must provide educational direction and opportunities for the medical and laboratory staff and participate in relevant educational programs of the institution. All personnel, including physicians and supervisors, should have the opportunity to further their knowledge and skills through on-the-job training, in-service education programs, workshops, institutes, and professional meetings. Education programs must be provided at defined intervals appropriate for the size and needs of the technical staff (TLC.11200) [2].

Much of the laboratory output is a result of, or involved with, research and development, regardless of whether those activities are internal or external, pure or applied, public or private, or clinical or technical. Consequently, the laboratory leadership must be involved in the direction and application of research and development appropriate to the facility. Also, many health care institutions carry additional formal educational responsibilities, such as training residents, fellows, nurses, medical technologists, and others; thus, the laboratory may well have a role in health care education, even if the department does not operate a pathology residency program. The Medical Laboratory Director needs to be aware of these other programs and be involved in the laboratory components of the training. Finally, given the necessary lead time for implementation of emerging technologies, the medical director needs to be involved in the strategic planning process applicable to the laboratory. In essence, the laboratory is critical across much of the health care enterprise, and the Medical Laboratory Director must ascertain appropriate scientific and technological education for all members of the laboratory team.

Administrative responsibilities

The administrative responsibilities of the Medical Laboratory Director fall largely into two broad categories: internal and external. The internal responsibilities center on day-to-day operations, leadership, and expectation setting. The external responsibilities center upon the establishment, maintenance, and communication of the laboratory relationship to the larger health care community of patients, payers, providers, regulators, and government.

Internal responsibilities

The Medical Laboratory Director participates in all managerial decisions and guides the day-to-day operation of the laboratory, ranging from selection of staff, choice of methods, purchase of equipment, quality assurance, quality control, safety, hours of operation, scheduling of staff, and use

management. He or she is expected to help define, implement, and monitor the accepted standards of performance in quality control, quality assurance, and cost-effectiveness of the laboratory service as well as the actual delivery of those services. One particular set of responsibilities centers on quality management activities: the Medical Laboratory Director must assure that the laboratory participates effectively in required quality management programs. These programs provide quality control systems and metrics that are designed to assure the medical reliability of laboratory data. Such processes are necessary for internal review to monitor effectiveness, identify opportunities for improvement, create action plans to address those weaknesses, and identify appropriate resources to bring them to resolution.

Many of the administrative and management responsibilities of the Medical Laboratory Director are similar to those of other directors. The Medical Laboratory Director must be involved with strategic planning to establish short- and long-term goals and allocate the resources appropriate to the medical environment in conjunction with the medical staff and administration of the hospital or institution. He or she must provide effective and efficient administration of the service, including budget planning and control, again in conjunction with the medical staff and administration. Much of the information used for third-party payments requires medical understanding and must be reviewed and monitored for accuracy. These obligations are part of providing cost-effective administration of all laboratory services.

The Medical Laboratory Director must further support laboratory personnel functioning as an integrated team, personally demonstrating leadership and team qualities. He or she needs to promote a stimulating and safe laboratory environment for team personnel to maintain a high quality of laboratory service. A well-oiled team requires a balance of interrelated components: staffing, workloads, education, training, and interindividual consideration. Sufficient qualified laboratory physicians, laboratory technologists, technicians, and other personnel are required to perform tests promptly and efficiently. Often overlooked and underappreciated is the need to have sufficient appropriately trained and experienced personnel to supervise the daily activities of the laboratory. Qualified technical staff should be on duty or available at all times that laboratory testing is being performed. In addition to orientation and training, an adequate continuing education program must be in place and documented. The Medical Laboratory Director must ascertain that all procedures and tests that are performed by the medical and technical staff are within the scope of education, training, and experience of the individual.

In other ways, the laboratory is a workplace like any other, where the director is responsible for establishing and maintaining a productive working environment. The physical infrastructure should provide sufficient space, equipment, and supplies to perform the required volume of work with optimal accuracy, precision, efficiency, timeliness, and safety. There need to be channels of communication within the laboratory operation as well as from

the laboratory to other hospital services, medical staff personnel, and relevant outside agencies. Communication practices need to be designed to assure confidentiality of laboratory data and monitored for compliance with accepted medical practices. Required documentation of records and reports must be maintained and filed appropriately in the medical record. Patient-related information must be accessioned, reported, and stored in confidential databases. As with any group of people working together, interpersonal dynamics can have effects well beyond the individual. Interpersonal relations should respect established personnel guidelines. Staff morale inherently reflects the aggregate effects of workload, compensation, working environment, and respect. Overall, the Medical Laboratory Director must have sufficient authority to implement and maintain the standards of practice.

One key responsibility is to ensure that the laboratory develops, implements, and maintains a quality system approach to laboratory testing to ensure accurate and reliable patient test results. In the quality system model, the laboratory focuses on comprehensive and coordinated efforts to achieve accurate, reliable, and timely testing services. The quality system includes all the laboratory policies, processes, procedures, and resources needed to achieve consistent, high-quality testing services. Integral to the quality system is quality assessment, which involves ongoing monitoring of each testing process used in the laboratory to identify errors or potential problems that could result in errors and taking corrective action and evaluating the corrective actions taken, to make sure that they are effective and prevent recurrence (TLC.10900) [2].

The Medical Laboratory Director is responsible for the laboratory's overall quality management program, including the monitoring of key indicators; investigation of problems, with corrective/preventive action as appropriate; maintenance of patient safety; analytic quality control; and ensuring the quality of tests referred to outside laboratories. The quality management program must effectively monitor essential performance characteristics of the laboratory; identify, investigate, and prevent recurrence of problems; and maintain patient safety. The quality management program must address preanalytic, analytic, and postanalytic activities. The plan must include monitoring of key indicators appropriate to the laboratory, as well as a program to investigate problems that may affect patient care, including implementation of corrective or preventive action as necessary (TLC.11000) [2]. The Medical Laboratory Director must ensure compliance with the requirements of the Occupational Safety and Health Administration of the US Department of Labor, state/local regulations, as well as other applicable safety regulations to maintain a safe laboratory environment (TLC.11400) [2]. The Medical Laboratory Director or designee must be directly involved in the selection of all laboratory equipment and supplies (TLC.11500) [2]. These standards are designed to ensure appropriate control over the process. The fact that economic issues are a major factor in these

selections does not relieve the Medical Laboratory Director of responsibility for ensuring the quality of the technical, clinical, and operational aspects of the laboratory.

The Medical Laboratory Director is responsible for the overall operation and administration of the laboratory. This does not mean that these duties must be performed personally, but rather that he or she must ensure the employment of competent qualified personnel, and some responsibilities can be delegated (see later discussion); however, the Medical Laboratory Director ultimately remains responsible and must ensure that all of the duties are performed properly and that applicable CLIA'88 regulations are addressed. Finally, despite the angst that some directors feel because of insufficient control, CLIA'88 does specify that the Medical Laboratory Director must ensure that sufficient numbers of appropriately educated, experienced, or trained personnel are available to provide consultation and supervision to ascertain accurate performance and reporting of test results. Supervisors must be employed by the laboratory and are responsible for reviewing new test procedures, making sure that they are included in the procedure manual, and confirming that the procedures are followed appropriately by personnel. Of course, all of this must be in accordance with the specific written duties and responsibilities for each employee.

External responsibilities

The external responsibilities center upon the establishment, maintenance, and communication of the laboratory relationship to the larger health care community of patients, payers, and providers, as well as the regulatory and legal aspects of health care. The laboratory is one of the most highly regulated services in any medical setting. The Medical Laboratory Director must be aware of and perform the duties and responsibilities consistent with the applicable standards of accreditation for laboratories that exist at a national or state level. Standards of practice must be consistent with the relevant regulatory agency: CAP, Joint Commission, state Department of Public Health, Center for Medicare and Medicaid Services, and so forth. These standards are not just for personnel qualification, but extend to the methods and systems in place to provide quality laboratory services. Depending upon the environment and complexity of a given laboratory, many of these standards are required for licensing, billing, and the provision of medical services.

The Medical Laboratory Director often is seen as the public "face" of the laboratory. Interactions with physicians, patients, administrators, and agencies are not only expected, but required. As such, he or she must be able to relate and function effectively with applicable accreditation and regulatory agencies, the medical community, and the patient population served. The Medical Laboratory Director is responsible to ensure communication

of laboratory data (TLC.10500) and to interact with government and other agencies as appropriate (TLC.10800) [2]. He or she also is responsible to the hospital oversight board, administration, or agency for the effective functioning of the laboratory. Those who use the laboratory services deserve and expect appropriate and timely responses to requests for testing as well as appropriate and timely delivery of results. As the public face of the laboratory, the Medical Laboratory Director must personally demonstrate leadership for, and support of, the staff as they function as an integrated team. Leadership also is important to develop and implement patient-focused laboratory services and delivery systems to optimize services to achieve the desired health outcomes for patients.

Delegation of responsibilities

Although the Medical Laboratory Director may be responsible for specific services, he or she need not perform all of those responsibilities personally (TLC.10400) [2]. **Box 1** lists the responsibilities of the Laboratory Director under CLIA'88. Authority to perform many services may be delegated, but the responsibility to make sure that those services are performed adequately remains with the Laboratory Director. For example, administrative functions may be delegated to qualified laboratory managers and supervisors. Medical and technical responsibilities may be delegated to physicians and other qualified laboratory personnel as appropriate. **Box 2** lists those responsibilities that cannot be delegated. No matter what director duties are delegated, the Medical Laboratory Director stands responsible to make sure that those duties are duly met and remains responsible for the overall operation and administration of the laboratory to ensure that quality patient care services are provided. This includes assuring the employment of competent personnel and assuring the adequacy of equipment, safety, laboratory policies, quality assurance, all testing (including proficiency testing), and test reports (42 CFR 493.1407 and 493.1445) [1]. Ultimately, however, some responsibilities may be delegated, but the overarching responsibility remains with the Medical Laboratory Director who must close the loop to confirm that delegated responsibilities are fulfilled.

CLIA'88 defines four different specific positions: Technical Consultant (42 CFR 493.1411 and 493.1413), Technical Supervisor (42 CFR 493.1447 and 493.1449), Clinical Consultant (42 CFR 493.1417, 493.1419, 493.1455, and 493.1457), and General Supervisor (42 CFR 493.1461, 493.1462, and 493.1463) [1]. For high-complexity testing, a General Supervisor must be available to provide day-to-day supervision of all testing personnel and reporting of test results as well as to provide on-site supervision for specific minimally qualified testing personnel when they are performing high-complexity testing. The Medical Laboratory Director may, if qualified, perform the duties of any of these positions. Some duties may be delegated in writing to other qualified individuals. The Medical Laboratory Director must

Box 1. Responsibilities of a Laboratory Director under Clinical Laboratories Improvement Amendments

If qualified, may perform duties of Technical Supervisor, Clinical Consultant, General Supervisor, and Testing Personnel or delegate these responsibilities to qualified personnel

If delegated, Laboratory Director remains responsible for ensuring that duties are properly performed

Must be accessible to laboratory to provide on-site, telephone, or electronic consultation as needed

May direct no more than five laboratories

Ensure quality laboratory services for all aspects of test performance (preanalytic, analytic, and postanalytic)

Ensure laboratory conditions are appropriate for testing performed and provide a safe environment in which employees are protected from hazards

Ensure test methodologies have the capability of providing quality results required for patient care

Ensure verification procedures are adequate to determine performance characteristics

Ensure personnel are performing test methods as required for accurate and reliable results

Ensure laboratory is enrolled in an approved proficiency testing program and that proficiency samples are tested as required, results are returned within the expected timeframes, reports are reviewed to evaluate laboratory's performance, and corrective action plans are followed when proficiency testing is unacceptable

Ensure that quality control and assurance programs are established and maintained

Ensure acceptable levels of analytical performance for each test

Ensure that patient test results are reported only when the test system is functioning properly and that remedial actions are taken and documented whenever significant deviations from established performance are identified

Ensure that test result reports include pertinent information required for interpretation

Ensure that consultation is available to clients on the quality of test results and their interpretation

Employ a sufficient number of laboratory personnel with appropriate education, experience, and training; properly supervise and accurately perform tests and report results

Ensure that before patient testing, all personnel have the appropriate education and experience, receive the training

appropriate for the type and complexity of services offered, and have demonstrated ability to perform testing operations reliably and to report accurate results

Ensure that policies and procedures are established for monitoring individuals who conduct any phase of testing (preanalytic, analytic or postanalytic), to assure they are competent and maintain their competency, and to identify needs for remedial training and continuing education to improve skills

Ensure that an approved, up-to-date procedure manual is available to all personnel

Specify, in writing, the responsibilities and duties of each consultant and supervisor, as well as each person engaged in all phases of testing and identify which examinations each individual is authorized to perform, whether supervision is required, and whether supervisory or director review is required before reporting test results

Adapted from Nichols JE, Karon BS. Preparing for a Laboratory Inspection. College of American Pathologists Excel Survey XL-E, 2007 and Laboratory Director Responsibilities CLIA brochure. Available at: <http://www.cms.hhs.gov/CLIA/downloads/brochure7.pdf>. Accessed July 19, 2007.

ensure that delegated duties are performed properly and that necessary individuals are accessible for consultation on-site or electronically.

The Laboratory Director can delegate in writing to a Clinical Consultant the responsibilities for ensuring that test reports include pertinent information for test interpretation and the availability for consultation concerning test results and the interpretation of those results as they relate to specific patient conditions.

A Technical Consultant (for moderate-complexity testing) or Technical Supervisor (for high-complexity testing) can have responsibility delegated to them for the duties listed in [Box 3](#).

For high-complexity testing, the Laboratory Director or Technical Supervisor may delegate to a General Supervisor, in writing, the responsibility to:

Evaluate high-complexity testing personnel annually

Review remedial action taken when test systems deviate from the laboratory's established performance specifications

Assure personnel orientation, training, competency, performance evaluations, and documentation

Assure patient test results are not reported until all corrective actions have been taken and the test system functions properly

Box 2. Director responsibilities that may not be delegated

Ensure quality services for all aspects of service
Ensure safe and adequate environmental conditions
Ensure Director-approved procedures are available to staff
Employ sufficient number of employees with appropriate education/training
Position descriptions for Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor
Ensure all delegated Director duties are properly performed
Ensure general supervisor provides on site supervision as required for high complexity testing personnel qualified under 42 CFR 493.1489(4)
Ensure test performance only within the limitations of the clinical laboratory license

Adapted from Nichols JE, Karon BS. Preparing for a Laboratory Inspection. College of American Pathologists Excel Survey XL-E, 2007 and Laboratory Director Responsibilities CLIA brochure. Available at: <http://www.cms.hhs.gov/CLIA/downloads/brochure7.pdf>. Accessed July 19, 2007.

Summary

The successful Medical Laboratory Director is actively involved in the operations of the laboratory, and, therefore, has the best vantage point to assure that others are performing the delegated duties appropriately. The successful Medical Laboratory Director has a mechanism in place for effective communication among management and laboratory personnel. He or she routinely reviews quality control and quality assessment activities to assure that problems occurring within the laboratory are identified and corrected and actively monitors those corrections for effectiveness and timeliness. He or she understands that if no apparent problems are identified through the quality control or quality assessment programs for a lengthy period, there might be a need to investigate whether more stringent or sensitive programs are warranted. He or she may regularly make changes in what is being monitored. If a quality assessment indicator is easily achieved, he or she understands that a novel or tighter indicator may lead to greater success.

The successful Medical Laboratory Director includes a mechanism as part of the quality assessment activities to provide for resolution of complaints received, regardless of the source. He or she also has a mechanism to resolve communication breakdowns that are internal and external to the laboratory. He or she ensures that laboratory staff and management are aware of CLIA'88 requirements and understand the role of quality systems. He or she understands that the laboratory is a horizontal service that

Box 3. Duties that can be delegated to a Technical Consultant or Technical Supervisor

Selection of appropriate test method selection to assure accurate results

Method verification to determine accuracy and precision

Assurance of proficiency testing enrollment in and compliance with approved program

Review of proficiency test reports and approve remedial action

Assurance of appropriate on-site supervision of high-complexity test performance

Establishment and maintenance of quality control and quality assurance programs

Monitoring of employee competency

Annual evaluation of high-complexity testing personnel

Review of remedial actions taken when necessary

Assurance and documentation of personnel training and competency

Assurance that an approved procedure manual is available to personnel responsible for testing

Adapted from Nichols JE, Karon BS. Preparing for a Laboratory Inspection. College of American Pathologists Excel Survey XL-E, 2007 and Laboratory Director Responsibilities CLIA brochure. Available at: <http://www.cms.hhs.gov/CLIA/downloads/brochure7.pdf>. Accessed July 19, 2007.

provides the informational underpinning of much of the health care delivery system and that errors and inefficiencies at such a fundamental level can have magnified consequences across many disciplines. In short, the successful Medical Director understands the CLIA '88 regulations and accreditation standards and applies his/her medical training with the goal of providing the highest quality laboratory testing realistically attainable.

References

- [1] Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Available at: <http://www.cms.hhs.gov/clia>. Accessed July 19, 2007.
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