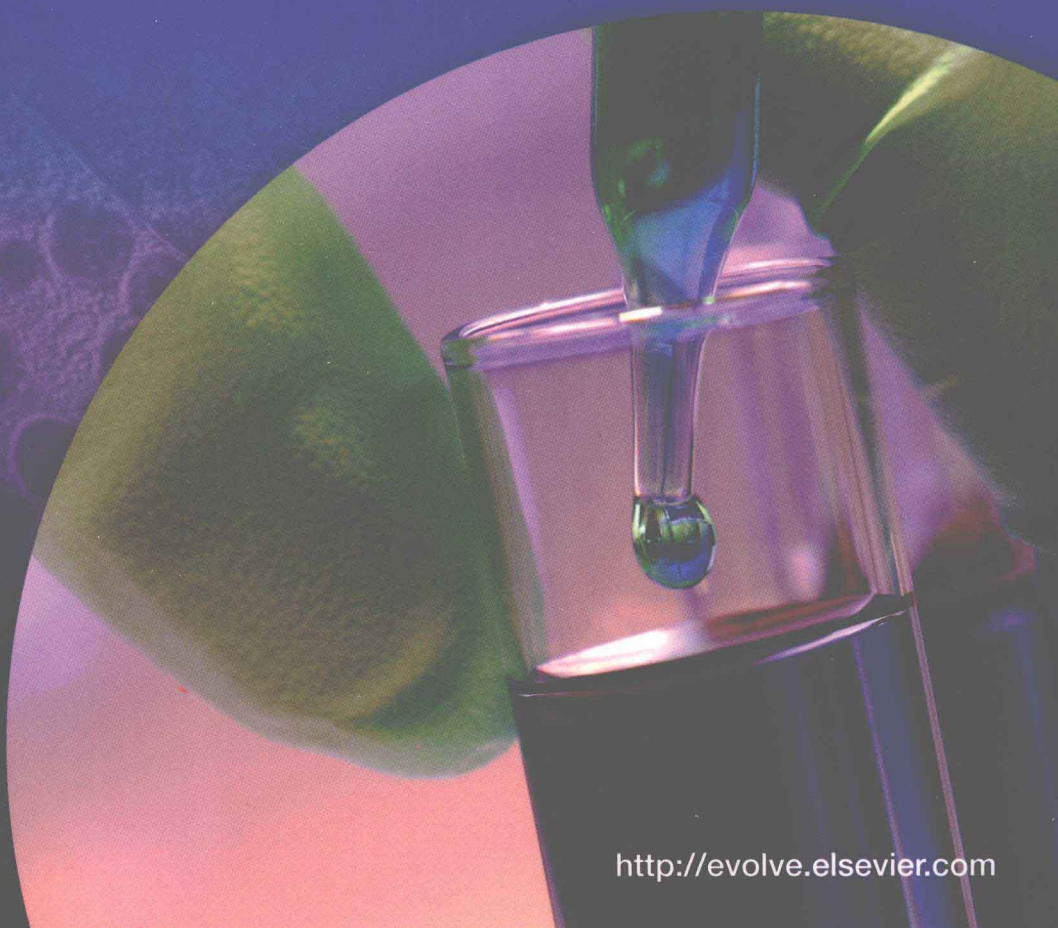
Mary Louise Turgeon

Linné & Ringsrud's

Clinical Laboratory Science

Sixth Edition

The Basics and Routine Techniques



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LINNÉ & RINGSRUD'S CLINICAL LABORATORY SCIENCE:
THE BASICS AND ROUTINE TECHNIQUES

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Mary Louise Turgeon, EdD, MT(ASCP) is an author, professor, and consultant in medical laboratory science. Her books are *Basic & Applied Clinical Laboratory Science*, ed 6 (2011), *Clinical Hematology*, ed 5 (2011), *Immunology and Serology in Laboratory Medicine*, ed 4, and *Fundamentals of Immunohematology*, ed 2. Foreign language editions have been published in Chinese, Spanish, and Italian.

Dr. Turgeon has fourteen years of university and fifteen years of community college teaching and program administration experience. She currently teaches on-line and on-the-ground in Massachusetts and Florida. Guest speaking and technical workshops complement teaching and writing activities. Her consulting practice (www.mlturgeon.com) focuses on new program development, curriculum revision, and increasing teaching effectiveness in the United States and internationally.

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Dedication

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Preface

The intention of this sixth edition of *Clinical Laboratory Science: The Basics and Routine Techniques* is to continue to fulfill the needs of medical laboratory scientists, medical laboratory technicians, clinical laboratory assistants, medical office assistants, physician assistants, and others for a comprehensive, entry-level textbook. This type of basic and clinical information is needed by anyone engaged in ordering or performing laboratory assays, or analyzing laboratory output data in various settings.

The purpose of this edition continues to be to describe the basic concepts in laboratory medicine, to outline the underlying theory of routine laboratory procedures done in clinical laboratories of varying sizes and geographic locations, and to present applicable case studies to help students integrate theory and practice. The major topical areas are divided into two sections: Part I: Basic Laboratory Techniques, and Part II: Clinical Laboratory Specializations.

This sixth edition capitalizes on the strengths of previous editions but presents extensively revised information and new content in most chapters. The pedagogy of the book includes a topical outline and behavioral objectives at the beginning of each chapter. The outlines and objectives should be of value to students in the organization of content and delineation of learning expectations. Review questions are at the end of each chapter. Case studies are provided at the end of each chapter in Part II. Illustrations and full-color photographs are used to visually clarify concepts and arrange detailed information.

Representative procedures published in the book or on the Evolve site are written in the format suggested by the CLSI. The use of this format familiarizes students with the recommended procedural write-up encountered in a working clinical laboratory.

WHAT IS SIGNIFICANTLY NEW IN THE SIXTH EDITION?

Part I: Basic Laboratory Theory and Techniques

- The history of Clinical Laboratory Science as a profession, certification and licensure, medical ethics and ISO 15189 kick off the new content in Chapter 1.
- Up-to-date safety information is always essential. In this edition, a discussion of the Americans with Disabilities act is included. New content in Chapter 2 includes the latest information on vaccinations such as H1N1, emerging knowledge about nosocomial infections such as MRSA, and new developments in disinfection and sterilization.
- Revised order of draw of venous blood specimens and new types of blood collection tubes are presented in Chapter 3. Information related to additives and gels, and conditions related to evacuated tubes has been added to this chapter.
- English-to-Metric conversions, hazardous management information system (HMIS), and updated aspects of chemical labeling has been added to Chapter 4.
- More review questions have been added to the traditional information in Chapters 5, 6, and 7.
- In Chapter 6, *Measurement Techniques in the Clinical Laboratory*, new labeling technologies and molecular techniques have been added as essential methods in modern testing.
- Chapter 8, *Quality Assessment and Quality Control in the Clinical Laboratory*, incorporates new information on Lean Six Sigma, latent errors, and preanalytical and postanalytical errors.
- Changes in Chapter 10, *Laboratory Information Systems and Central Laboratory Automation*, are reflected in information on bar coding and radio frequency devices, autoverification of laboratory results, middleware, and molecular and genetic testing and laboratory information systems.

Part II: Clinical Laboratory Specializations

The body of knowledge of clinical laboratory theory and practice continues to expand. In this sixth edition, new information has been added to every chapter.

- Chapter 11, *Introduction to Clinical Chemistry*, features expanded descriptions of acid-base balance, and the anion gap, osmolality and gap, and diabetes.
- Chapter 12, *Principles and Practice of Clinical Hematology*, incorporates expanded coverage

of postanalytical errors, automated digital cell morphology, critical values, and histograms.
- Additional content on pre-analytical variable in coagulation testing is presented in Chapter 13, *Introduction to Hemostasis*.
- Chapter 14, *Renal Physiology and Urinalysis*, features more content on quality control, and newer types of containers, preservatives, and collection methods. In addition, content on the history of urinalysis and modern urinalysis is incorporated.
- Chapter 15, *Examination of Body Fluids*, a discussion of amniotic fluid has been added.
- Chapter 16, *Introduction to Medical Microbiology*, presents more microorganism identification characteristics.
- Chapter 17, *Immunology and Serology*, features expanded coverage of phagocytosis, prozone and postzone, antinuclear antibody photomicrographs.
- The final chapter, Chapter 18, *Immunohematology and Transfusion Medicine*, incorporates gel technology, automation, and the principles of antibody identification.

The appendices now include a list of Spanish-English Conversational Phrases for Phlebotomists as well as approved curriculum competencies for medical laboratory assistants.

No attempt has been made to replace textbooks that exclusively focus on a specific clinical laboratory specialty and written at a more detailed level for medical laboratory science (MLS) students. The sixth edition of this text is appropriate for introductory clinical laboratory science courses, laboratory techniques or basic core laboratory courses, or as a reference book. Comments from instructors, other professionals, and students are welcome at m.turgeon@neu.edu.

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Acknowledgments

My objective in writing *Linné & Ringsrud's Clinical Laboratory Science: The Basics and Routine Techniques*, Sixth Edition, is to continue the work started by Linné and Ringsrud to share comprehensive basic concepts, theory, and applications of clinical laboratory science with beginning clinical laboratory students or others who have a need for laboratory information. This book has provided me with a challenging opportunity to expand my knowledge of the latest medical laboratory content and to share my generalist skill set and teaching experience with others.

Special thanks to my former colleagues at Northeastern University, Carol Finn, MS, M(ASCP) and Patricia A. Wright, BS, MT (ASCP), SBB, Blood Bank Supervisor, University of Massachusetts Memorial Medical Center.

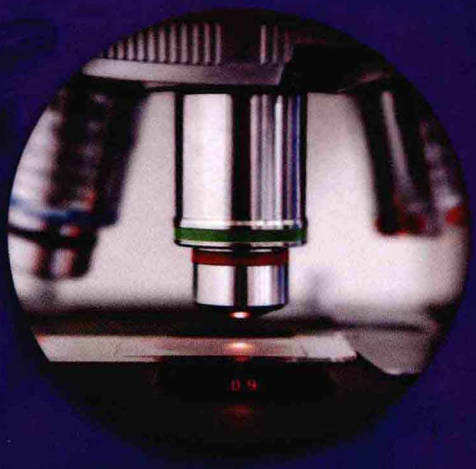
Thanks to Ellen Wurm-Cutter, who was my editor for this and other books. Working with her is always a pleasure. Rachel McMullen deserves recognition for her attention to detail in the production of this book.

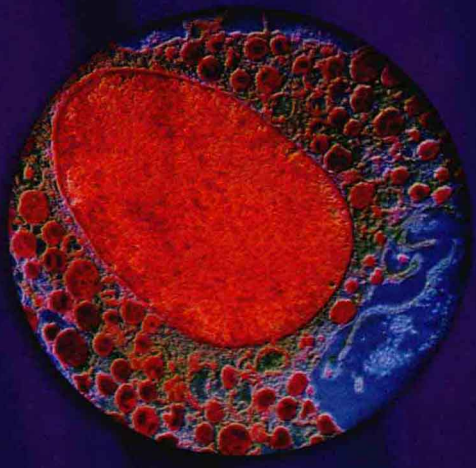
Mary L. Turgeon

Contents

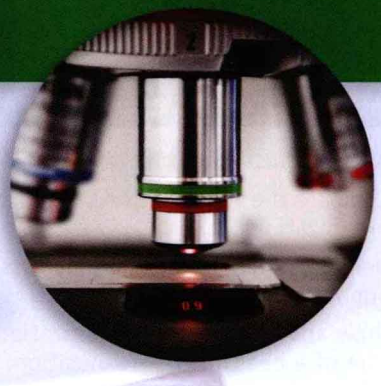
PART I

Basic Laboratory Techniques





CHAPTER 1



FUNDAMENTALS OF THE CLINICAL LABORATORY

Learning Objectives

At the conclusion of this chapter, the student will be able to:

- Compare the functions of the professional organizations.
- Define the term *ethics*, and discuss medical applications.
- Draw and describe the organizational structure of a health care organization.
- Name the typical departments of a clinical laboratory.
- Name and describe clinical laboratory staffing and functions.
- Define the acronyms OSHA, CLIA '88, CMS, TJC, CLSI, and CAP.
- Compare and contrast the uses of various sites for laboratory testing: central laboratory, point of care, physician office laboratory, and reference laboratory.
- Describe the importance of federal, state, and institutional regulations concerning the quality and reliability of laboratory work.
- Briefly explain the CLIA '88 regulations and the classification of laboratory testing by complexity of the test: waived, moderately complex, highly complex, and provider-performed microscopy.
- Describe the purpose of participation in CLIA '88–mandated proficiency testing programs and how they relate to quality assessment.
- Name and describe alternate sites of laboratory testing.
- Name and describe nonanalytical and analytical factors in quality assessment.
- Name the three most frequent inspection deficiencies over time for all CLIA-approved laboratories.
- Describe proficiency testing.
- Discuss ISO Standards in the clinical laboratory.
- Name three medical-legal issues, and discuss issues associated with each.
- Compare the four newest directions in laboratory testing.

CLINICAL LABORATORY SCIENCE

Clinical laboratory testing plays a crucial role in the detection, diagnosis, and treatment of disease. Medical laboratory scientists (MLS) and medical laboratory technicians (MLT) collect and process specimens and perform chemical, biological, hematologic, immunologic, microscopic, molecular diagnostic, and microbial testing. They may also collect and prepare blood for transfusion. Laboratory aides may also be members of the laboratory team (see Appendix A for a description of laboratory aide topics and objectives for training).

After collecting and examining a specimen, laboratory professionals analyze the results and relay them to physicians or other health care providers. In additional to routine testing, duties in the clinical laboratory include developing and modifying procedures, and monitoring programs to ensure the accuracy of test results.

The Bureau of Labor Statistics *Occupational Outlook Handbook* for Clinical Laboratory Technologists and Technicians states, "Rapid job growth and excellent job opportunities are expected. Most jobs will continue to be in hospitals, but employment will grow in other settings, as well."[1]

HISTORY OF CLINICAL LABORATORY SCIENCE AS A PROFESSION

Rudimentary examinations of human body fluids date back to the time of the ancient Greek physician Hippocrates around 300 BC, but it was not until 1896 that the first clinical laboratory was opened in a small room equipped at a cost of $50 at Johns Hopkins Hospital, Baltimore, Maryland. The diagnostic and therapeutic value of laboratory testing was not yet understood. Many physicians viewed clinical laboratories simply as an expensive luxury that consumed both valuable space and time.

Discovery of the causative agents of devastating epidemics such as tuberculosis, diphtheria, and cholera in the 1880s and the subsequent development of tests for their detection in the late 1890s highlighted the importance of laboratory testing.

Original Credentialing and Professional Organizations

World War I caused a critical shortage of qualified laboratory assistants to staff laboratories. This urgent situation prompted the creation of

diversified training programs to meet the growing need for trained laboratory professionals.

The American Society of Clinical Pathologists (ASCP) created the Board of Registry (BOR) in 1928 to certify laboratory professionals and later the Board of Schools (BOS). Individuals who passed the BOR's registry exam were referred to as "medical technologists," identified by the acronym "MT (ASCP)."

In 1933, the American Society of Clinical Laboratory Technicians (ASCLT) was formed. Later, this organization was renamed the American Society of Medical Technologists (ASMT) and, finally, today's designation as the American Society for Clinical Laboratory Science (ASCLS). The catalyst for establishment of ASCLT was the desire for a greater degree of autonomy and control of the direction of the profession by nonphysician laboratory professionals. ASCLS is proud to champion the profession and ensure that other members of the health care field—as well as the public—fully recognize the contributions of clinical laboratory professionals.

In 1973, as a result of pressure from the U.S. Office of Education and the National Commission on Accrediting, ASCP agreed to disband the BOS and turn over its functions to an independently operated and governed board, the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). In 1977, the autonomous certification agency, the National Certification Agency for Medical Laboratory Personnel (NCA) was formed.[2]

Individual Professional Recognition

During the 1960s, new categories of laboratory professionals joined generalist medical technologists in performing the daily work of the clinical laboratory. These categories were created to help cope with an increased workload. The category of certified laboratory assistant (CLA) was developed as a one-year certificate program; the category of medical laboratory technician (MLT) was developed as a two-year associate degree program. Simultaneously, specialist categories in chemistry, microbiology, hematology, and blood banking were created. Specialists certified in cytotechnology, histotechnology, laboratory safety, and molecular pathology/molecular biology have evolved as well. Technicians certified as donor phlebotomists or phlebotomy technicians are part of the laboratory team. Pathologists' assistants[3] are another category of specialty certification. Certification as a Diplomat in Laboratory Management is available.[3]

Newest Professional Recognition

In September 2009, a historic step was taken when the NCA and ASCP merged into a single professional agency. Generalists are now referred to as *medical laboratory scientists* (MLSs). The technician-level designation has not changed but continues to be designated as *medical laboratory technicians* (MLTs). Continuing education is now a requirement for certified professionals.

Additional Individual Professional Certification and Licensure

Many employers prefer or are required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations (see later discussion) to hire laboratory staff who are certified by a recognized professional association. In addition to the newly merged ASCP route, the American Medical Technologists (AMT) also offer certification.

Numerous states currently require licensure or registration of laboratory personnel, with other states considering it, thus further ensuring the integrity of the profession. The requirements vary by state and specialty. Information on licensure is available from state departments of health or boards of occupational licensing.

MEDICAL ETHICS

What is *ethics*? According to the Merriam-Webster dictionary, the definition of ethics includes the discipline dealing with what is good and bad, or a set of moral principles. Personal ethics are based on values or ideals and customs that are held in high regard by an individual or group of people. For example, many people value friendship, hard work, and loyalty.

Ethics also encompasses the principles of conduct of a group or individual, such as professional ethics. ASCLS endorses a professional Code of Ethics (Box 1-1), which states that all laboratory professionals have a responsibility for proper conduct toward the patient, colleagues and the profession, and society. In addition, ASCLS has a Pledge to the Profession (Box 1-2).

Situational ethics is a system of ethics by which acts are judged within their contexts instead of by categorical principles. Hospitals have ethics committees to evaluate situational ethics cases. Individual laboratory professionals may need to make decisions based on personal or professional values. An example of a five-step model for decision making is presented in Box 1-3.

HEALTH CARE ORGANIZATIONS

Modern health care organizations have many different configurations, depending on the geographic region and market, mix of patients (e.g., age), overall size, and affiliations. The size of health care

BOX 1-1

American Society for Clinical Laboratory Science Code of Ethics

Preamble

The Code of Ethics of the American Society for Clinical Laboratory Science sets forth the principles and standards by which clinical laboratory professionals practice their profession.

I. Duty to the Patient

Clinical laboratory professionals are accountable for the quality and integrity of the laboratory services they provide. This obligation includes maintaining individual competence in judgment and performance and striving to safeguard the patient from incompetent or illegal practice by others.

Clinical laboratory professionals maintain high standards of practice. They exercise sound judgment in establishing, performing, and evaluating laboratory testing.

Clinical laboratory professionals maintain strict confidentiality of patient information and test results. They safeguard the dignity and privacy of patients and provide accurate information to other health care professionals about the services they provide.

II. Duty to Colleagues and the Profession

Clinical laboratory professionals uphold and maintain the dignity and respect of our profession and strive to maintain a reputation of honesty, integrity, and reliability. They contribute to the advancement of the profession by improving the body of knowledge, adopting scientific advances that benefit the patient, maintaining high standards of practice and education, and seeking fair socioeconomic working conditions for members of the profession.

Clinical laboratory professionals actively strive to establish cooperative and respectful working relationships with other health care professionals, with the primary objective of ensuring a high standard of care for the patients they serve.

III. Duty to Society

As practitioners of an autonomous profession, clinical laboratory professionals have the responsibility to contribute from their sphere of professional competence to the general well-being of the community.

Clinical laboratory professionals comply with relevant laws and regulations pertaining to the practice of clinical laboratory science and actively seek, within the dictates of their consciences, to change those which do not meet the high standards of care and practice to which the profession is committed.

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BOX 1-2

Pledge to the Profession

As a clinical laboratory professional, I strive to:

- Maintain and promote standards of excellence in performing and advancing the art and science of my profession
- Preserve the dignity and privacy of others
- Uphold and maintain the dignity and respect of our profession
- Seek to establish cooperative and respectful working relationships with other health professionals
- Contribute to the general well-being of the community

I will actively demonstrate my commitment to these responsibilities throughout my professional life.

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BOX 1-3

Five Steps to Decision Making

1. State the problem.
2. Establish personal and professional values regarding the problem.
3. List alternative possibilities for problem resolution.
4. Rank order your choice of possible solutions, and compare this list to a ranked-order list of applicable personal and professional values.
5. Rank order a list of the short- and long-term consequences of the problem.
6. Make a dicussion.

Courtesy Cecile Sanders, Austin Community College, Austin, TX.

organizations range from the very large tertiary care–level teaching hospitals, to community hospitals, to freestanding specialty clinics or phlebotomy drawing stations.

A common organizational structure for a hospital (Fig. 1-1) includes the chief executive officer (CEO) and the board of trustees, who set policy and guide the organization. The chief operating officer (COO) is responsible for implementing policies and daily activities. Other high-level positions can include the chief financial officer (CFO), chief information officer (CIO), and chief technology officer (CTO), depending on the size of a health care organization. A variable number of vice presidents (VPs) have several departments reporting to them. Organizations usually have vice