

LESSON 1-1

Introduction to the Clinical Laboratory

LESSON OBJECTIVES

After studying this lesson, the student will:

- Explain the function of a medical or clinical laboratory.
- Discuss the organization of a typical hospital clinical laboratory.
- Describe the functions of the different levels of laboratory personnel.
- List the major departments of a typical clinical laboratory and name a test that would be performed in each department.
- List three examples of nonhospital clinical laboratories and describe the function of each.
- Explain how clinical laboratories are regulated.
- Explain the relationships between Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), and clinical laboratories.
- Discuss benefits of point-of-care (POC) testing.
- Explain how the Health Insurance Portability and Accountability Act (HIPAA) affects the laboratory and laboratory workers.
- Discuss the use and value of electronic health records (EHRs).
- Describe the purpose and scope of quality assessment programs in the clinical laboratory.
- Explain the reason for proficiency testing.
- Explain the purpose of laboratory accreditation.
- Define the glossary terms.

GLOSSARY

- accessioning** / the process by which specimens are logged in, labeled, and assigned a specimen identification code
- accreditation** / a voluntary process in which an independent agency grants recognition to institutions or programs that meet or exceed established standards of quality
- American Association of Blood Banks (AABB)** / international association that sets blood bank standards, accredits blood banks, and promotes high standards of performance in the practice of transfusion medicine
- anticoagulant** / a chemical or substance that prevents blood coagulation
- bacteriology** / the study of bacteria
- blood bank** / clinical laboratory department where blood components are tested and stored until needed for transfusion; immunohematology department; transfusion services; also the refrigerated unit used for storing blood components
- Centers for Disease Control and Prevention (CDC)** / central laboratory for the national public health system
- Centers for Medicare and Medicaid Services (CMS)** / the agency within the Department of Health and Human Services (DHHS) responsible for implementing CLIA '88
- Clinical and Laboratory Standards Institute (CLSI)** / an international, nonprofit organization that establishes guidelines and standards of best current practice for clinical laboratories; formerly National Committee for Clinical Laboratory Standards (NCCLS)
- clinical chemistry** / the laboratory section that uses chemical principles to analyze blood and other body fluids
- Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)** / a federal act that specifies minimum performance standards for clinical laboratories
- coagulation** / the process of forming a fibrin clot
- College of American Pathologists (CAP)** / organization that offers accreditation to clinical laboratories and certification to clinical laboratory personnel
- COLA** / agency that offers accreditation to physician office laboratories, hospitals, clinics and other healthcare facilities; formerly the Commission on Office Laboratory Accreditation
- Department of Health and Human Services (DHHS)** / the governmental agency that oversees public healthcare matters; also called HHS
- electronic health record (EHR)** / comprehensive, portable electronic patient health record
- electronic medical record (EMR)** / a digital form of a patient chart created in a physician's office or a hospital where a patient received treatment
- epidemiology** / the study of the factors that cause disease and determine disease frequency and distribution
- Food and Drug Administration (FDA)** / the division of the Department of Health and Human Services (DHHS) responsible for protecting the public health by ensuring the safety and efficacy of foods, drugs, biological products, medical devices, and cosmetics
- Health Care Financing Administration (HCFA)** / see Centers for Medicare and Medicaid Services (CMS)

hematology / the study of blood and the blood-forming tissues

HIPAA / Health Insurance Portability and Accountability Act of 1996

immunohematology / the study of the human blood groups; in the clinical laboratory, often called blood banking or transfusion services

immunology / the branch of medicine encompassing the study of immune processes and immunity

Joint Commission (JC) / an independent agency that accredits hospitals and large healthcare facilities; formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Laboratory Response Network (LRN) / a nationwide network of public and private laboratories coordinated by Centers for Disease Control and Prevention (CDC) with the ability for rapid response to threats to public health

microbiology / the branch of biology dealing with microbes

mycology / the study of fungi

National Committee for Clinical Laboratory Standards (NCCLS) / see Clinical and Laboratory Standards Institute (CLSI)

pathologist / a physician specially trained in the nature and cause of disease

phlebotomist / a healthcare worker trained in blood collection

physician office laboratory (POL) / small medical laboratory located within a physician office, group practice, or clinic

plasma / the liquid portion of blood in which the blood cells are suspended; the straw-colored liquid remaining after blood cells are removed from anticoagulated blood

point-of-care testing (POCT) / testing outside the traditional laboratory setting; also called bedside testing, off-site testing, near-patient testing, or alternative-site testing

proficiency testing (PT) / a program in which a laboratory's accuracy in performing analyses is evaluated at regular intervals and compared to the performance of similar laboratories

Provider-Performed Microscopy Procedures (PPMP) / a certificate category under CLIA '88 that permits a laboratory to perform waived tests and also permits specified practitioners to perform on-site microscopy procedures

quality assessment (QA) / in the laboratory, a program that monitors the total testing process with the aim of providing the highest-quality patient care

reference laboratory / an independent regional laboratory that offers routine and specialized testing services to hospitals and physicians

serology / the study of antigens and antibodies in serum using immunological methods; laboratory testing based on the immunological properties of serum

serum / the liquid obtained from blood that has been allowed to clot

standard operating procedure (SOP) / established procedure to be followed for a given operation or in a given situation with the purpose of ensuring that a procedure is always carried out correctly and in the same manner

virology / the study of viruses

waived test / a category of test defined under CLIA '88 as being simple to perform and having an insignificant risk for error