

LESSON

1-1

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 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.
- Explain how clinical laboratories are regulated.
- Explain the relationship between CMS and CLIA '88.
- Explain how the HIPAA affects the laboratory and laboratory workers.
- Describe the purpose and scope of quality assessment programs in the clinical laboratory.
- Explain the purpose of 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 a private, 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

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 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; the laboratory department that performs hemostasis testing
- College of American Pathologists (CAP)** / agency that offers accreditation to clinical laboratories and certification to clinical laboratory personnel
- Commission on Office Laboratory Accreditation (COLA)** / agency that offers accreditation to physician office laboratories
- Department of Health and Human Services (DHHS)** / the governmental agency that oversees public health care matters; commonly called HHS
- 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 assuring 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 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 health care facilities (formerly known as the Joint Commission on Accreditation of Healthcare Organizations [JCAHO])
- Laboratory Response Network (LRN)** / a nationwide network of laboratories coordinated by the 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)
- parasitology** / the study of parasites
- pathologist** / a physician specially trained in the nature and cause of disease
- phlebotomist** / a health care 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, or alternate-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 Procedure (PPMP)** / a certificate category under CLIA '88
- quality assessment (QA)** / in the laboratory, a program that monitors the total testing process with the aim of providing the highest-quality patient care; a synonym for "quality assurance"
- 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
- virology** / the study of viruses

INTRODUCTION

Laboratories that perform chemical and microscopic tests on blood, other body fluids, and tissues are called *clinical* or *medical laboratories*. These laboratories play a major role in patient care and are found in a variety of settings, both government and private. A clinical laboratory can be in a large institution, offer sophisticated services, and employ many skilled workers who interact daily with patients and other allied health personnel in the institution. Clinical laboratories can also be small, with only one or two employees.

Today, clinical laboratories, as well as other health care delivery systems, face a variety of challenges. These include coping with rapidly rising costs, maintaining quality personnel, keeping up with advancing technologies, and complying with increased governmental regulations. These issues must be addressed without sacrificing the quality of patient care. This lesson surveys the types of clinical laboratories and describes their organization, function, and regulation.

TYPES OF CLINICAL LABORATORIES

Clinical laboratories can be placed into two groups: hospital laboratories and nonhospital laboratories. Although most people think of hospitals when they think of clinical laboratories, laboratories can also be in clinics, group practices, physician offices, nursing homes, veterinary offices, government agencies, industry, and military installations. Some clinical laboratories, such as regional reference laboratories, are independent of medical facilities.

In 2006, the Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), listed more than 196,000 private and commercial laboratories as providing services to humans in the United States. Table 1-1 shows the numbers of U.S. clinical laboratories by type of facility. This number does not include laboratories limited to research or veterinary laboratories.

Hospital Laboratories

Clinical laboratories are found in private hospitals, university teaching hospitals, and government-operated institutions such as military hospitals and veterans' hospitals. The clinical laboratory is one of many hospital departments (Figure 1-1). The level of services available from a hospital laboratory is usually determined by the size of the hospital. A laboratory in a small hospital (less than 100 beds) may perform only very routine test procedures. Complicated or infrequently requested tests may be sent to reference laboratories.

In a clinical laboratory in a medium-size hospital (up to 300 beds), routine tests and many more complicated test procedures are performed. Only the most recently developed tests, infrequently requested tests, or tests with high levels of complexity would need to be sent to reference laboratories.

Clinical laboratories in large hospitals (more than 300 beds) handle large volumes of work and perform complex tests (Figure 1-2).

TABLE 1-1. Numbers and types of clinical laboratories performing tests on humans registered by CMS, June 2006 (From Division of Laboratory Services, CMS, DHHS)

TYPE OF LABORATORY	NUMBER	PERCENT OF TOTAL
Ambulatory surgical center	3809	1.93%
Community clinic	6610	3.34%
Comp. outpatient rehabilitation facility	260	0.13%
Ancillary testing site in health care facility	2749	1.40%
Renal dialysis facility	3978	2.02%
Health fair	508	0.26%
Health maintenance organization	667	0.34%
Home health agency	9654	4.89%
Hospice	1740	0.88%
Hospital	8677	4.41%
Independent	5329	2.71%
Industrial	1702	0.86%
Insurance	45	0.02%
Intermediate care/mentally retarded	969	0.49%
Mobile laboratory	1120	0.57%
Pharmacy	4085	2.10%
School/student health facility	1873	0.95%
Skilled nursing facility/nursing facility	14,737	7.47%
Physician office	106,528	54.09%
Other practitioner	2437	1.24%
Tissue bank/repository	35	0.02%
Blood bank	366	0.19%
Rural health clinic	1170	0.59%
Federally qualified health center	389	0.20%
Ambulance	2760	1.40%
Public health laboratory	181	0.09%
Other	14,595	7.41%

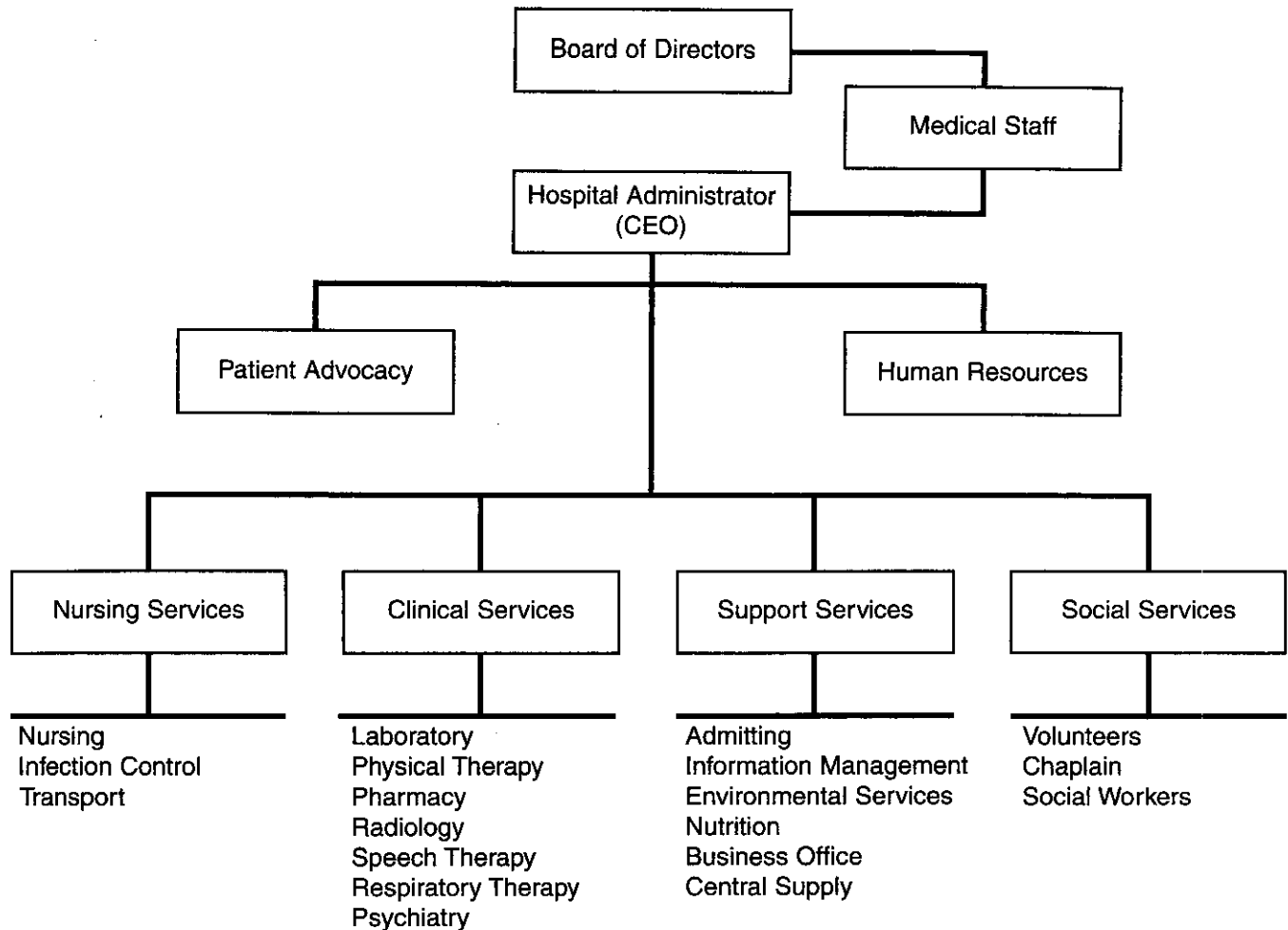


FIGURE 1-1 Example of a hospital organizational chart



FIGURE 1-2 A clinical laboratory in a large hospital

Nonhospital Clinical Laboratories

Nonhospital clinical laboratories can be publicly (government) or privately operated. They provide a variety of services and employment for many skilled workers. In the United States in 2005, most clinical laboratories were in nonhospital settings (Table 1-1).

Physician Office Laboratories

Physician office laboratories (POLs) are laboratories in a physician's office or small clinic. In 2006, 54% of clinical laboratories listed with the DHHS were classified as POLs. The increased availability of rapid-test kits and small, easy-to-operate analyzers has broadened the scope of testing in the POL. Several common laboratory tests, such as hemoglobin, hematocrit, urine reagent strip, pregnancy, blood glucose, and occult blood, can be performed in the POL by multiskilled personnel such as medical assistants (Table 1-2).

Reference Laboratories

Reference laboratories are usually privately owned, regional laboratories that do high-volume testing and offer a wide variety of tests. Large hospitals use reference laboratories primarily to perform complex or infrequently ordered tests. Small hospitals or physicians' offices use their services for a wide range of tests. Reference laboratories provide courier service to transport specimens from the collection site to the testing laboratory.

Government Laboratories—Federal

The central laboratory for the national public health system is the Centers for Disease Control and Prevention (CDC) in Atlanta,

TABLE 1-2. Examples of analytes for which there are waived tests under CLIA (as published by FDA, 2005)

Hemoglobin by copper sulfate
Hemoglobin by single instrument with direct readout
Blood glucose by meters cleared for home use
Glycosylated hemoglobin (HbA1c)
Fecal occult blood
Spun hematocrit
Ovulation tests by color comparison
Urine pregnancy tests by visual color comparison
Urinalysis reagent strip
Microalbumin
Rapid strep test from throat swab
Erythrocyte sedimentation rate
Immunoassay for <i>Helicobacter pylori</i>
Prothrombin time
Fructosamine
Cholesterol; high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol
Infectious mononucleosis antibodies

Georgia. This agency provides consulting services to state public health laboratories as well as to individual physicians. The CDC provides educational materials and safety guidelines for workers in a variety of health care areas as well as for the general public.

Epidemiology is another important function of the CDC. Data are gathered concerning the origin, distribution, and occurrence of various diseases, and outbreaks are investigated to determine the causes. This function of the CDC has gained much public attention because of its role in investigating emerging infectious diseases that have appeared worldwide in recent years.

The CDC also coordinates the Laboratory Response Network (LRN). This laboratory network was established to ensure that state and private laboratories are equipped to respond effectively to threats to public health, such as bioterrorism events or emerging infectious diseases.

Government Laboratories—State

Each U.S. state and territory has a clinical laboratory operated, usually, by the state's department of public health. These state laboratories provide testing and consulting services to hospitals, physicians, and clinics within the state.

Services available from state laboratories vary from state to state. In general, state laboratories perform tests mandated by state regulations, for example, premarital blood tests and phenylketonuria (PKU) testing of newborns. State laboratories also offer tests not routinely available in other laboratories such as culture of fungi, viruses, and mycobacteria (which include the pathogens causing tuberculosis); tests for parasites; confirmatory tests for

reportable infectious diseases such as AIDS; and some environmental testing. Special-case specimens to be sent to the CDC for testing are usually sent via state public health laboratories.

REGULATION OF CLINICAL LABORATORIES

All clinical laboratories, including POLs (but excluding research laboratories), are regulated by both federal and state agencies. The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), a revision of the Clinical Laboratory Improvement Act of 1967, specifies the minimum performance standards for all clinical laboratories. The objective of CLIA '88 is to ensure quality laboratory testing. Even though CLIA was passed in 1988, the amendments have been continually revised, updated, clarified, and refined since that time.

The Division of Laboratory Services, under the CMS (www.cms.hhs.gov/clia/) has the responsibility for implementing the CLIA '88 Program. Any laboratory performing laboratory tests on humans, except for research laboratories, must obtain a certificate from CMS to be allowed to operate.

Under CLIA '88, laboratories are classified as performing:

- Waived tests
- Tests of moderate and high complexity
- Provider-Performed Microscopy Procedures (PPMP)

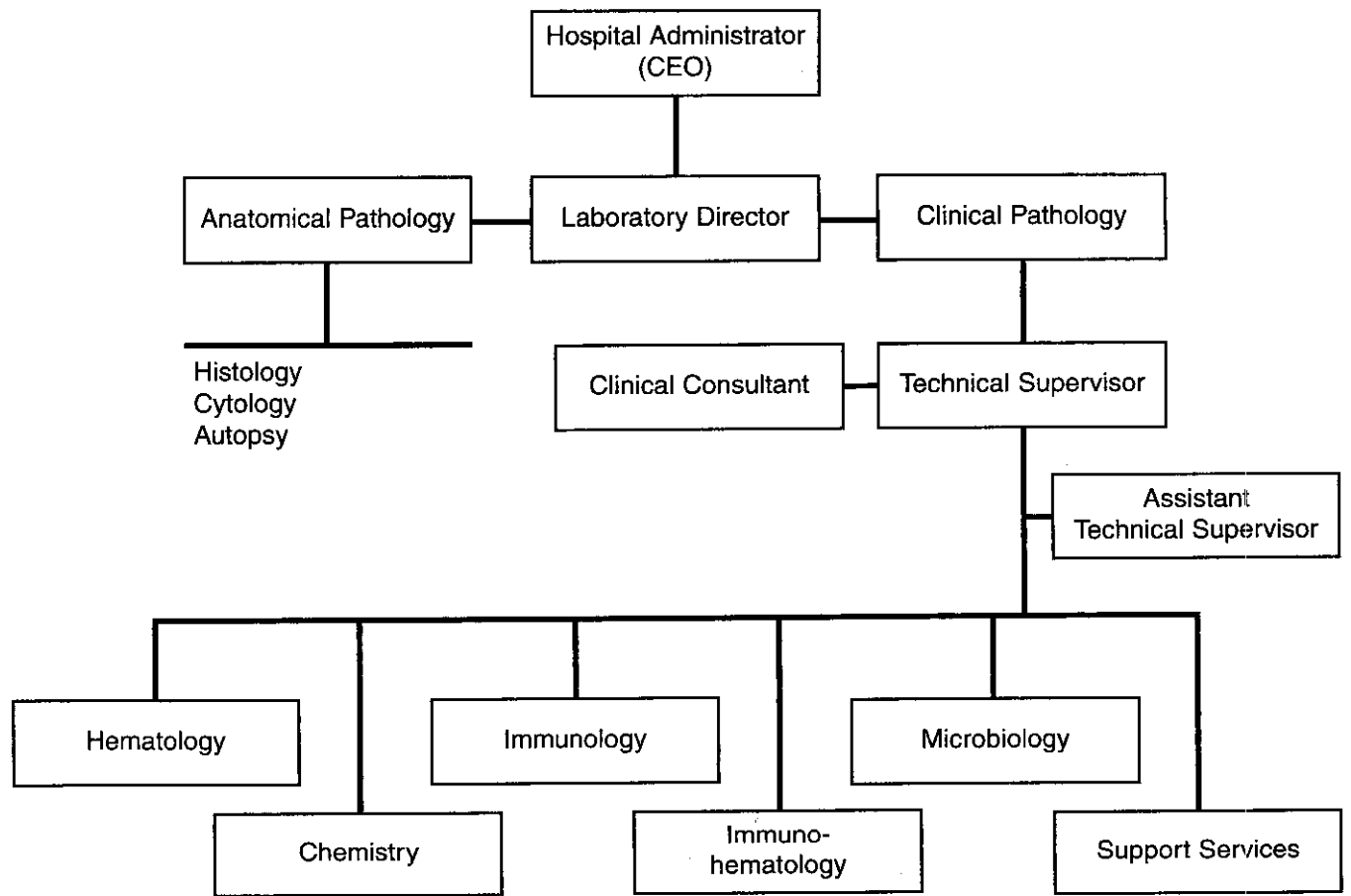
The classifications are based on the difficulty or complexity of the test procedures and the level of training required to accurately perform the tests. Laboratory personnel standards differ for each of these categories. The more complex the test, the more highly trained the testing personnel must be. Each laboratory must obtain a certificate stating its category. The five certificates are (1) Certificate of Waiver, (2) Certificate for PPMP, (3) Registration Certificate, (4) Certificate of Compliance, and (5) Certificate of Accreditation. Table 1-3 explains conditions under which each certificate would be issued.

Under the CLIA '88 law, laboratories with a certificate of waiver can only perform tests that are determined by the CDC or the Food and Drug Administration (FDA) to be so simple that there is little risk of error. These are called *waived tests*, and examples of some analytes for which there are waived tests are listed in Table 1-2. Because of advances in technology, the number and types of waived tests have increased, and the number of laboratories performing waived tests has grown tremendously since CLIA '88 implementation. Laboratories with a PPMP certificate perform microscopy-based tests during the course of a patient visit on specimens that are not easily transportable. Examples of PPMP include urine microscopic examination and wet mounts.

Many POLs perform only waived tests; some others may perform more complex (nonwaived) tests. Most hospital laboratories perform moderate- to high-complexity tests. In 2004, of the more than 180,000 certified laboratories, over 74,000 performed nonwaived tests. This means that, to comply with the law, these facilities must adhere to mandated personnel guidelines, comprehensive recordkeeping, and quality assess-

TABLE 1-3. Types of certificates issued under CLIA '88 and the activity(ies) each certificate permits

CERTIFICATE	ACTIVITY PERMITTED
Certificate of Waiver	Permits a laboratory to perform only CLIA-waived tests
Certificate of Registration	Permits the laboratory to conduct moderate- or high-complexity laboratory testing (or both) until the laboratory is determined by survey to be in compliance with CLIA regulations
Certificate of Compliance	Issued to a laboratory holding a Certificate of Registration after an inspection finds the laboratory to be in compliance with all applicable CLIA regulations
Certificate of Accreditation	Issued to a laboratory that has been accredited by a CMS-approved accrediting organization
PPMP	Issued to a laboratory in which a physician, mid-level practitioner, or dentist performs no tests of complexity other than the microscopy procedures; this certificate also permits the laboratory to perform waived tests

**FIGURE 1-3** Organizational chart of a typical hospital laboratory

ment programs; participate in proficiency testing programs; and be subject to government inspections. Laboratories performing moderate- to high-complexity tests must have a certificate of registration, compliance, or accreditation.

States can enact state-specific regulations regarding the operation of laboratories. However, state standards must be at least as stringent as federal regulations and must not violate or counteract federal regulations.

ORGANIZATION OF THE HOSPITAL LABORATORY

The organization schemes of most hospital laboratories follow a general outline (Figure 1-3) that can vary slightly depending on the size of the laboratory. In recent years, some laboratories have changed department and personnel titles to reflect the terminology used in the CLIA '88 rules. Table 1-4 lists personnel titles as

TABLE 1-1. Job titles of clinical laboratory personnel as listed in CLIA '88 Final Rule and commonly used equivalent titles

CLIA '88 JOB TITLE	EQUIVALENT JOB TITLE
Laboratory director	Laboratory director (usually a pathologist)
Technical supervisor	Laboratory manager, chief technologist
Clinical consultant	Consultant
Technical consultant or general supervisor	Department head, section head, section supervisor, technical specialist
Testing personnel	Medical technologist, clinical laboratory scientist, medical laboratory technician, clinical laboratory technician, laboratory assistant

stated in CLIA '88 and gives the commonly used equivalent titles. The personnel qualifications for each category are specified in the Clinical Laboratory Improvement Amendments of 1988, Final Rule, *Federal Register*, Vol. 7, No. 40, February 28, 1992.

Clinical Laboratory Personnel

Laboratory Director

The director of the hospital laboratory has customarily been a pathologist, a physician specially trained in the nature and cause of disease. Hospital pathologists usually oversee two branches of pathology, anatomical pathology and clinical pathology. The anatomical pathology department includes cytology, histology, and autopsy services. The clinical laboratory department can also be called clinical pathology or clinical laboratory services.

Under CLIA '88, persons other than pathologists can qualify to be clinical laboratory directors. The type of CMS certificate held by the laboratory determines the qualifications a director must have. In general, the laboratory director must be licensed by the state in which the laboratory operates; hold the degree of doctor of medicine, doctor of osteopathy, or an earned doctorate in a related clinical field; hold certification from an appropriate body; and have supervisory and clinical laboratory experience. The laboratory director has ultimate responsibility for all laboratory operations.

Small hospitals may not have a full-time pathologist on staff or on-site. Depending on the qualifications of the laboratory director, laboratories in these hospitals can be required to contract with certified individuals to serve as *clinical consultants* and/or *technical consultants*. These consultants assist the laboratory director in matters of test appropriateness and interpretation or in technical matters relating to test methods.

Technical Supervisor/Laboratory Manager

Directly under the laboratory director's authority is the technical supervisor or laboratory manager (Figure 1-3). This is someone educated in the clinical laboratory sciences who has additional business or management training or experience.

The technical supervisor (laboratory manager) is responsible for the day-to-day operation of the laboratory. The technical supervisor is also responsible for setting personnel standards, establishing training and evaluation procedures, establishing appropriate quality assessment programs, observing and documenting employee performance and competence, and making sure that all regulatory mandates are followed. The supervisor is responsible for making available to all personnel an up-to-date procedure manual containing instructions for every procedure performed in the laboratory. The Clinical and Laboratory Standards Institute (CLSI) develops standards of current best practice for clinical laboratory procedures. Laboratory procedure manuals must follow CLSI standards. (CLSI was formerly known as the National Committee for Clinical Laboratory Standards, or NCCLS).

General Supervisor/Department Head

Each department has a general supervisor or department head responsible for the quality of work performed in the department, training employees, and evaluating employee performance. General supervisors report to the technical supervisor.

Testing Personnel

Testing personnel perform the laboratory analyses (Figure 1-4). These include medical technologists/clinical laboratory scientists and medical laboratory technicians/clinical laboratory technicians. Nonlaboratory personnel such as medical assistants and nursing staff often perform tests in POLs or other settings outside the laboratory proper. Clinical laboratory personnel qualifications are discussed in Lesson 1-2, The Clinical Laboratory Professional.

Departments of the Clinical Laboratory

The number of departments in clinical laboratories varies. Clinical chemistry, hematology, microbiology, blood bank, and support services (phlebotomy and specimen processing) usu-



FIGURE 1-4 Testing personnel in a clinical laboratory

ally operate as departments or sections, each with its own department head or general supervisor. The subdivisions within each department differ from one laboratory to another. Large laboratories often have separate departments for urinalysis, coagulation, immunology, and parasitology (Figure 1-3).

Hematology

Most hematology tests involve studying the cellular components of blood. Hematology procedures can be qualitative or quantitative. The *quantitative* procedures include counts of the various blood components, such as the number of leukocytes (white blood cells), erythrocytes (red blood cells), or platelets. These counts can be performed manually but are usually performed on a cell counter or hematology analyzer.

In *qualitative* procedures, blood components are observed for qualities such as cell size, shape, and maturity. Using a microscope, a laboratory worker can view a blood smear to determine the types of leukocytes present; estimate the size, shape, and hemoglobin content of erythrocytes; or estimate the number of platelets. Any abnormalities are noted during microscopic examination of the blood smear, including immature leukocytes or erythrocytes.

Hematocrit and hemoglobin are tests commonly performed to help diagnose anemia. Many analyzers are capable of performing several hematological procedures simultaneously.

In large laboratories, complicated tests such as special stains to classify leukemic cells might be performed in a hematology section called *special hematology*. Some tests in special hematology are manual tests.

Coagulation. Coagulation tests are used to diagnose and monitor patients who have defects in their blood-clotting mechanism or are being treated with anti-clotting drugs. Coagulation tests may be performed in the hematology department or, in large laboratories, in a separate department. In past years, automated coagulation testing systems were used primarily in larger laboratories. However, the availability of small, easy-to-use coagulation analyzers allows even small POLs to have the capability of performing coagulation procedures. Plasma, the liquid portion of anticoagulated blood, is the specimen used for most coagulation studies.

Urinalysis. Like coagulation, urinalysis can be a separate department in a large laboratory or a subdivision of another department, usually hematology or chemistry. In the urinalysis department, physical, chemical, and microscopic examinations of urine specimens are performed. These tests can be performed manually or using automated methods.

Clinical Chemistry

In the clinical chemistry department, test procedures are often performed on serum, the liquid part of blood remaining after a clot has formed. Tests can also be performed on plasma, urine, and other body fluids such as spinal fluid and joint fluid.

Procedures performed in the clinical chemistry department include blood glucose, cholesterol, assays of heart and liver enzymes, and electrolytes (chloride, bicarbonate, potassium, and sodium).

Clinical chemistry is the largest department in most laboratories and can have one or more subdivisions. Common subdivisions

are *special chemistry* and *toxicology*. Procedures such as electrophoresis are performed in special chemistry. In toxicology, blood or urine can be analyzed to determine the drug involved in an overdose, blood levels of prescribed drugs, and hormone levels.

The number of chemistry analyzers has grown rapidly in the last several years (see Lesson 6-3). Most of these analyzers provide a wide range of test procedures yet are simple to operate. Thus, it is possible for even the smallest laboratory to perform some routine chemistry tests.

Immunology

Immunology can be a separate department or, in small laboratories, a part of another department such as blood bank or microbiology. In the past this department was called serology because serum was the specimen most often used in the tests. In immunology, many tests are based on antigen-antibody methods. Among tests performed in this section are those for pregnancy, arthritis, and autoimmune diseases. Tests for infectious mononucleosis, HIV infection, influenza, hepatitis, sexually transmitted diseases, and other infectious diseases are also performed.

Blood Bank/Transfusion Services

The blood bank department may also be called immunohematology or transfusion services. Procedures performed in this department are critical to patient well-being. If a transfusion is required, the patient's ABO group and Rh type are determined by blood bank technologists. Stored units of donor blood are then tested to determine which units would be compatible for transfusion into the patient. The blood bank department might also have the capability to process donated blood into specialized components.

Microbiology

The microbiology department is responsible for culturing and identifying microorganisms. Bacteriology procedures make up the majority of the work in this department. Bacteria can be isolated from specimens such as sputum, wounds, blood, urine, or other body fluids by inoculating the specimen to culture media. Organisms that grow in the culture are identified, and susceptibility tests are performed to determine the most effective antibiotic treatment. This is done by exposing the bacterial culture to different antibiotics and observing their effect on the organism's growth. Automated systems that can detect growth of an organism, identify an organism, and determine its antibiotic susceptibility are widely used in bacteriology.

Procedures involving virology, the study of viruses, and mycology, the study of fungi, are usually performed in the microbiology department. Often specimens are cultured in the hospital laboratory, and identification is performed by reference laboratories. Because cultures of pathogenic fungi as well as mycobacteria must be handled with special care, specimens suspected of containing these organisms are usually inoculated to media and then sent to a reference laboratory for identification.

Parasitology. In parasitology, usually a part of the microbiology department, patient specimens are examined for parasites. Fecal samples are examined microscopically for evidence of intestinal parasites such as intestinal amoeba, tapeworms, or hookworms.

Immunological tests are performed to detect parasite antigens in fecal samples. Tests for blood parasites, such as the malarial parasite, are usually performed in the hematology department.

Laboratory Support Services

Laboratory tests begin with the laboratory request form, which must be completed before the test is performed (Figure 1-5). This can be a written request or a computer-generated request. After the request is received, the laboratory will begin the test process—collecting the specimen; performing the test; and interpreting, recording, reporting, and charting results. Most hospital laboratories have a separate department responsible for collecting and processing specimens. This department is called by a variety of names such as support services, phlebotomy, or specimen collection and processing. Phlebotomists are the laboratory personnel who collect the blood specimens; sometimes this responsibility is shared by nursing personnel.

In small laboratories, specimens are usually taken directly to the appropriate laboratory department. In larger laboratories, specimens are delivered to a central accessioning area where they are processed, logged into the computer, and given a specimen identification code before being distributed to the departments for testing. Many hospitals have pneumatic delivery systems that provide rapid delivery of specimens from the patient room or nursing station, outpatient clinic, surgery, emergency room, or intensive care unit to the clinical laboratory or other department.

Laboratory Information Systems

Large laboratories have computerized laboratory information systems (LIS) that improve efficiency and reduce errors. In hospitals, the LIS can be integrated with the institution-wide computer system. Computerization in the laboratory and hospital has made specimen identification and tracking more error-proof. Specimens are labeled with preprinted bar-coded labels that match bar-coded test requisitions and patient identification bracelets. Data can be entered directly into the computer system using bar-code scanners. Even small laboratories usually have a method to preprint specimen labels with patient data. Advantages of laboratory information systems include:

- Charting errors can be eliminated.
- Efficiency is improved.
- Abnormal or unusual test results are automatically identified.
- Specimens can be matched to test results.
- Unauthorized testing and reporting is prevented.

Point-of-Care Testing

Rapid advancements in technology make possible rapid changes in all aspects of health care. One of the major changes in the clinical laboratory has been the implementation and increased use of point-of-care testing (POCT). POCT brings the laboratory test to the patient rather than obtaining a specimen from the patient and transporting it to the laboratory for testing. This makes laboratory test results available more rapidly, providing improved patient care.

POCT is used in settings such as clinics, health maintenance organizations (HMOs), nursing homes, physician offices,

emergency rooms, intensive care units, and surgery suites. POCT is also referred to as bedside testing, near-patient testing, off-site testing, or alternate-site testing.

The evolution of small, simple-to-use analyzers that require only one drop, or less, of specimen has led to widespread POCT implementation. Handheld portable analyzers can measure substances such as hemoglobin, glucose, cholesterol, and electrolytes. Most require only a drop of blood, usually obtained by fingerstick. Most POCT tests are CLIA-waived.

The advent of POCT has created the opportunity for more collaboration between the laboratory and other members of the health care team. Although nonlaboratory personnel from the nursing service or surgery or emergency room teams may perform the tests, the laboratory is usually responsible for selecting instrumentation, training personnel, developing procedure manuals, and monitoring quality assessment procedures and instrument maintenance.

QUALITY ASSESSMENT IN THE LABORATORY

For many years, clinical laboratories have had programs in place to monitor the quality of laboratory results. These program requirements expanded under CLIA '88 and associated legislation. All laboratories now must have comprehensive programs to evaluate and improve the overall laboratory performance. These programs have evolved through many changes, beginning as quality control (QC), progressing to quality assurance and broader programs such as total quality management (TQM) and continuous quality improvement (CQI). The name recommended by CMS is quality assessment (QA), part of a comprehensive quality system (QS).

The QA programs are incorporated into each department's procedure manual and day-to-day operation. One person in the laboratory, usually a supervisory person such as the assistant laboratory manager, may be responsible for implementing the QA programs throughout the laboratory and documenting the results. Every aspect of a test procedure, from ordering the test and collecting the specimen to reporting of results, falls under the QA umbrella. QA responsibilities can also include managing POCT or off-site and satellite laboratory testing; evaluating personnel, training, and providing continuing education; updating procedure manuals; monitoring compliance with regulatory agencies; keeping records; documenting equipment maintenance, calibration, and repairs; and participating in proficiency testing programs.

All institutions receiving Medicare or Medicaid funds are required to develop and maintain a QA program. The intent of this requirement is to improve health care, focusing on patient safety and ways to reduce medical errors. Lesson 1-7 describes in detail how QA is used in the clinical laboratory.

Proficiency Testing

Laboratories performing moderate- or high-complexity testing are required by CLIA '88 to participate in an approved proficiency testing (PT) program. Participation in these programs is a part of a laboratory's QA program. PT programs send "unknown" samples to laboratories at regular intervals. The laboratory performs specific tests on the unknowns and reports the results to the PT



LABORATORY ORDER REQUEST

Last Name Doe		First Jane	Middle	Social Security Number		Birthdate
Physician			Date/time drawn		Phlebotomist	
ICD-9 code(s)				Bill to: <input type="checkbox"/> Insurance <input type="checkbox"/> Office <input type="checkbox"/> Patient		

PROFILES	ICD-9 CODE #	INDIVIDUAL PROCEDURES	ICD-9 CODE #	INDIVIDUAL PROCEDURES	ICD-9 CODE #
<input type="checkbox"/> BASIC METABOLIC PROFILE		<input checked="" type="checkbox"/> HEMATOLOGY / COAGULATION		<input checked="" type="checkbox"/> CHEMISTRY PROCEDURES	
Basic Metabolic Profile Includes: Calcium Carbon Dioxide Chloride Creatinine Glucose Potassium Sodium Urea Nitrogen		CBC		Potassium (K+)	
		PT (Protime) w/INR		Glucose	
		PTT		BUN (Urea Nitrogen)	
<input type="checkbox"/> ELECTROLYTE PANEL		Hgb (Hemoglobin)		Calcium	
Electrolyte Panel Includes: Sodium Potassium Chloride Carbon Dioxide		HCT (Hematocrit)		Creatinine	
		ESR (sed rate)		PSA (Prostatic Specific Antigen)	
		Hemoglobin A1-C		PSA Screen	
<input type="checkbox"/> METABOLIC PANEL COMPREHENSIVE		<input checked="" type="checkbox"/> SEROLOGY		TSH	
Comprehensive Metabolic Panel Includes: Albumin Chloride Potassium Bilirubin, total Creatinine Protein, total BUN Glucose Sodium Calcium Phosphatase, alkaline ALT/SGPT AST/SGOT		RPR		T-3 Uptake	
		CRP (C-Reactive Protein)		T4, Free (Free Thyroxine)	
		ASO (with titer)		T4, (Total Thyroxine)	
		H. pylori		CK - Total	
<input type="checkbox"/> HEPATIC FUNCTION PANEL		RA (Rheumatoid factor)		TIBC (Total Iron Binding Capacity)	
Hepatic Function Panel Includes: Albumin Phosphatase, alkaline Bilirubin, total Protein, total Bilirubin, direct ALT/SGPT AST/SGOT		ANA (anti-nucleic antibody)		Amylase	
		SSA/SSB		Vitamin B-12	
		<input checked="" type="checkbox"/> URINE PROCEDURES		Folate	
		Urinalysis		Digoxin Level	
<input type="checkbox"/> LIPID PROFILE		Urinalysis Culture w/sensitivity		Theophylline Level	
Lipid Profile Includes: Cholesterol Triglycerides HDL LDL		24-hour Urine Protein		OTHER PROCEDURES	
		24-hour Urine Creatinine with clearance		1.	
MICROBIOLOGY & CULTURES		24-hour Urine, Creatinine		2.	
Culture, Throat		Random Urine, Sodium		3.	
Culture, Sputum		Random Urine, Potassium		4.	
Strep A Screen (swab)		Random Urine, Chloride		5.	
Gram Stain (Note Source)		Random Urine, Myoglobin		6.	
Source:		Random Urine, Osmolality		7.	

Physician's Signature: _____ Date: _____

Medicare Advanced Beneficiary Notice

Section 1862(a)(1) of the Medicare Law states that Medicare will only pay for services that it determines are "reasonable and necessary." If the service is determined not to be "reasonable and necessary" by Medicare program standards, payment will be denied.

Medical Record - White Copy

Lab - Yellow Copy

Physician's Office - Pink Copy

FIGURE 1-5 Example of a laboratory request form

agency, which evaluates them for accuracy and for the laboratory's performance compared to other laboratories in the program.

Participation in a PT program is an important part of a laboratory's QA program and allows the laboratory to have confidence in testing methods and to identify deficient areas. The PT agency provides documentation of performance for accrediting and regulatory agencies.

Accreditation

Accreditation is a voluntary process by which an independent agency grants recognition to institutions or programs that meet or exceed established standards of quality. Most health care institutions seek accreditation because it enhances the institution's reputation and gives the public a way to assess the institution's quality of care.

An institution desiring accreditation invites the accrediting agency to inspect its facility to determine if established standards are being met. Several agencies accredit hospitals and departments within hospitals, including the Joint Commission (JC), College of American Pathologists (CAP), American

Association of Blood Banks (AABB), and the Commission on Office Laboratory Accreditation (COLA) (Table 1-5 and Appendix D). These agencies have *deemed status* with CMS, which means that accreditation by these agencies is recognized as meeting all government standards under CLIA '88.

PRIVACY ISSUES

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA). From this act, a privacy rule was issued, providing federal protections for personal health information and guaranteeing a patient's right to privacy. This was a response to the potential for loss of privacy created by the increased use and availability of electronic patient records as computers came into wider use in health care recordkeeping. The privacy rule requires health care facilities to use all necessary measures and procedures to ensure that patient information remains private and confidential. At the same time, the rule permits disclosure of information that is needed for patient care. All health care agencies now request that a patient be informed of their privacy rights, and patients must give written permission for health information to be shared, even with family members.

Much communication in laboratories and health care institutions is facilitated by computers. Most laboratories have a central laboratory computer information system through which tests are requested and test results are reported and entered into a database. Use of computers in health care contributes to efficiency and improved patient care. However, it also presents the opportunity for violation of patient privacy, whether intentional or unintentional. Computers with patient information must be password protected so that only authorized persons can access information. Computer monitors should be positioned so that visitors, other patients, and nonauthorized personnel cannot view the screen. The use of specimen identification codes, instead of patient names, helps protect patient privacy.

It must be emphasized to employees that all patient information must remain private and confidential, and must be shared only with authorized persons to facilitate and improve patient care.

TABLE 1-5. Accrediting agencies with deemed status under CLIA '88.

ACCREDITING AGENCY	ENTITIES ELIGIBLE FOR ACCREDITATION
Joint Commission (JC)	Hospitals
College of American Pathologists (CAP)	Clinical laboratories
American Association of Blood Banks (AABB)	Blood bank departments
Commission on Office Laboratory Accreditation (COLA)	POLs

CRITICAL THINKING

Timothy is a medical assistant working in a small POL. His laboratory operates under a certificate of waiver. The physician requests a microscopic examination of urine for patient Mary Smith. During Timothy's medical assistant training, he learned to perform microscopic examination of urine, classified by CLIA as a moderate complexity test.

1. What is the appropriate action for Timothy to take?
 - a. Tell the physician that it is not possible to have the test performed.
 - b. Send the specimen to a laboratory approved for performing moderate to high-complexity testing.
 - c. Perform the test and report the results to the physician.
2. Explain your answer.

SUMMARY

Clinical laboratories are found both in hospitals and in nonhospital settings. Laboratories must meet specific qualifications to gain government permission to operate. They are regulated by CLIA '88, which contains standards and regulations designed to protect patients, laboratory personnel and other health care workers, and society as a whole. The aims are to ensure that laboratory tests are done in a manner that assures reliable results and to be sure that laboratory employees work in a safe, healthy environment. Laboratory personnel must also adhere to HIPAA guidelines that guarantee protection of patient privacy.

The clinical laboratory is a dynamic workplace and an important partner on the health care team. As rapid changes continue in medical technology and health care delivery systems, laboratories must be able to adjust to future trends. The increase in POCT and use of computerized accessioning methods are two examples of current laboratory trends.

The organization of a clinical laboratory is determined by the size of the laboratory, the types and number of tests performed, and the qualifications of personnel. Hospital laboratories usually contain several departments, such as hematology, chemistry, microbiology, and blood bank. Each department is responsible for performing specific tests in its area and maintaining a QA program.

The clinical laboratory has a role in fostering good channels of communication in the laboratory and also between the laboratory and physicians, other departments in the hospital, and other health care providers. By educating health care partners about clinical laboratory medicine, such as appropriateness of tests and interpreting and understanding laboratory test results, the best interest of the patient is served.

- List three locations of clinical laboratory facilities other than in hospitals.
- Explain the job functions of the laboratory director, technical supervisor, and department head or general supervisor.
- What is the purpose of CLIA '88?
- What federal agency is responsible for implementing CLIA '88?
- What are waived tests?
- List the five certificates issued under CLIA '88, and state the activities each certificate permits.
- What is the advantage of proficiency testing?
- How do laboratories become accredited?
- Define accessioning, accreditation, American Association of Blood Banks, bacteriology, blood bank, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Clinical and Laboratory Standards Institute, clinical chemistry, Clinical Laboratory Improvement Amendments of 1988, coagulation, College of American Pathologists, Commission on Office Laboratory Accreditation, Department of Health and Human Services, epidemiology, Food and Drug Administration, Health Care Financing Administration, hematology, HIPAA, immunohematology, immunology, Joint Commission, Laboratory Response Network, microbiology, mycology, National Committee for Clinical Laboratory Standards, parasitology, pathologist, phlebotomist, plasma, point-of-care testing, physician office laboratory, Provider-Performed Microscopy Procedure, proficiency testing, quality assessment, reference laboratory, serology, serum, and virology.

REVIEW QUESTIONS

- What is the function of a clinical laboratory?
- Draw an organizational chart of a typical hospital laboratory.
- Name five major departments found in a hospital laboratory.
- Name two procedures performed in the hematology department.
- Name two tests performed in the chemistry department.
- How does the HIPAA affect workers in the laboratory?

STUDENT ACTIVITIES

- Complete the written examination on this lesson.
- Interview an employee of a clinical laboratory. Inquire about the laboratory's organization and the types of tests performed. Obtain various laboratory test report forms and note the types of tests performed in each department.
- Tour a hospital or reference laboratory in your area.
- Visit a POL and find out what types of tests are performed there.

WEB ACTIVITIES

- Select five analytes from Table 1-2. Visit the CMS Web site and list the brands of test kits that qualify as waived for each of the five.
- Visit the CDC Web site and obtain information about the LRN. Describe the levels of laboratories in the program and the ways in which various laboratories participate.
- Find Web sites of three clinical laboratories. Note the types of information provided on each Web site.