

CDC 4T051N

**Medical Laboratory
Journeyman—
Administration and
Chemistry**

**Volume 1. Laboratory
Administration and Clinical
Chemistry Theory**



**Air Force Institute for Advanced Distributed Learning
The Air University
Air Education and Training Command**

Author: MSgt Chris Lange and MSgt Karla L. Puterbaugh
382d Training Squadron
882d Training Group (AETC)
382d TRS/XYAC
917 Missile Road, Suite 3
Sheppard Air Force Base, Texas 76311–2263
DSN: 736–4089
E-mail address: chris.lange@sheppard.af.mil

Instructional Systems

Specialist: James L. Coleman

Editor: Sandra W. Wynn

Air Force Institute for Advanced Distributed Learning
The Air University (AETC)
Maxwell Air Force Base, Gunter Annex, Alabama 36118–5643

THE AIR FORCE medical laboratory technician should possess and demonstrate the technical ability to effectively deliver quality laboratory results. Also required is knowledge of administrative tasks and the Air Force instructions that govern many of these tasks. Career Development Course (CDC) 4T051N has three volumes; a breakdown follows with a detailed description of volume 1. Volume 1 is the first volume of three career development courses for upgrade to the 5 skill level. Unit 1 briefly reviews the medical laboratory mission, unit 2 delves into quality assurance, unit 3 covers safety, unit 4 discusses all aspects of specimen collection and medical terminology, unit 5 looks at clinical chemistry theory, unit 6 provides an overview of laboratory instrumentation, and, finally, unit 7 allows you to gain insight into the laboratorian's role regarding biological warfare and terrorism. Volume 2, *Clinical Chemistry*, will cover a plethora of chemistry analyte testing methods and principles. Volume 3, *Renal Function and Procedures*, will guide you through all aspects of urinalysis.

A glossary of terms, abbreviations, acronyms, and symbols used in this volume is included for your use.

Also included in this volume is appendix A, titled "The Periodic Table of the Elements." Refer to it as the text directs.

A bibliography is included at the end of this volume.

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This volume is valued at 24 hours and 8 points.

Acknowledgment

PREPARATION of this volume was aided through the cooperation and courtesy of the W. B. Saunders Company, who furnished the Periodic Table of the Elements, which is seen in appendix A. Permission to reprint this informational table is gratefully acknowledged.

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Many thanks go to the Medical Laboratory Apprentice Course staff for their assistance in preparing this volume. Thanks especially to Captains Colleen Halupa and Erin Morris as well as my predecessor, MSgt Karla Puterbaugh, who all aided immeasurably to the development of this course.

NOTE:

In this volume, the subject matter is divided into self-contained units. A unit menu begins each unit, identifying the lesson headings and numbers. After reading the unit menu page and unit introduction, study the section, answer the self-test questions, and compare your answers with those given at the end of the unit. Then do the unit review exercises.

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WELCOME to the Medical Laboratory Journeyman Career Development Course (CDC)! You are about to embark on a journey through the different disciplines of the medical laboratory. These CDCs (three courses—10 volumes) focus on the refinement of your clinical skills through knowledge of procedural theory and administrative principles. To be successful, you must possess not only scientific and technical expertise but also administrative expertise. If your laboratory is to meet mission accomplishment, you must be prepared to accept the challenge of performing a significant number of technical and administrative tasks. At this time in your career, you are probably quite familiar with the technical tasks involved in the medical laboratory career field, but you may be less acquainted with the administrative tasks. Administrative tasks include documenting and maintaining quality assurance reports; conducting and monitoring training of new personnel; requisitioning and maintaining supplies and equipment; preparing and maintaining publications; performing safety inspections and reporting accidents; and/or accomplishing all other types of administrative records. This first volume of the CDCs covers most of these tasks. With a brief overview of the medical laboratory mission, medical ethics, patient and professional relationships, and Air Force publications, you'll undertake your journey.

1–1. The Medical Laboratory

Before you begin, it is important that we define the term “medical laboratory.” You are aware that the medical field, as well as the military, has its own “jargon.” Sometimes we use our jargon or slang incorrectly. Therefore these CDCs define terms associated with a particular section or subject in the laboratory. *Dorland’s Illustrated Medical Dictionary* defines a *clinical laboratory* as “a laboratory for measurement and examination of materials derived from the human body for the purpose of providing information on diagnosis, monitoring prevention, or treatment of disease.” You may be assigned to a variety of Air Force laboratories during your career. Nonetheless, for this course, we use the term “clinical laboratory” to identify a facility that provides chemical, microbiological, hematological, or serological examinations on human body fluids. Now that you have your foundation, let’s start with the mission of the Air Force Clinical Laboratory Services.

001. The mission

As you can assume, we can make only a broad laboratory mission statement because the mission of each medical treatment facility (MTF) is different depending on its mission and size. Therefore, the mission of the clinical laboratory is to meet the mission of the MTF.

Clinical laboratory mission

The laboratory accomplishes this mission by providing accurate, reliable, and timely services that aid in the diagnosis, treatment, and prevention of diseases affecting the health and welfare of all patients; whether they are active duty military personnel, retirees, dependents, or civilians. The extent of the services provided depends upon the mission of the MTF. The size of the MTF alone, however, does not always dictate the nature and extent of laboratory services provided. Some Air Force laboratories are unequaled in the services they provide, while others send or ship specimens to other laboratories

for routine and/or special analyses. This leads us into the various types of reference laboratories that may support your laboratory.

Reference laboratories

No matter how large the facility is, it would be impossible to do all the diverse tests available. Due to this, reference laboratories play a vital role in support of any laboratory and, in turn, the MTF.

Military reference laboratories

Laboratories forward tests or examinations that they are unable to perform to other medical groups in their geographical area (Air Force, Army, or Navy) and/or the Institute of Environmental Safety, Occupational Health, and Risk Analysis (also known as the EPILAB), Brooks AFB, Texas. The major overall mission of epidemiological services is to provide professional consultation and referral capability, conduct epidemiological surveys and investigations, and perform specified analytical procedures in support of Air Force medical activities. Epidemiological services are established to prevent and control diseases among military and civilian personnel and eligible dependents.

Forensic toxicology examinations

Located on the grounds of the Walter Reed Army Medical Center in Washington, D.C., the Armed Forces Institute of Pathology (AFIP) performs all Air Force forensic toxicology examinations that are a result of an aircraft accident or incident. This institute serves as the central pathology laboratory for the Department of Defense (DOD) and certain other federal agencies. We list a sampling of the variety of services provided by the AFIP below. The AFIP is not limited solely to performing toxicological studies and autopsies.

- Maintains a consultation service for the diagnosis of pathologic tissue for the DOD, for other agencies, and for civilian pathologists.
- Serves as the reviewing authority of pathologic tissue for the Army, Navy, and Air Force.
- Conducts research and instruction in the broad field of pathology as well as maintaining a medical illustration service.
- Trains qualified and selected enlisted personnel of the armed forces in pathologic techniques, medical photography, medical arts, and museum activities.
- Donates or loans educational material to federal and civilian medical services.
- Operates the American Registry of Pathology, a cooperative medical research and education enterprise.

NOTE: All non-aircraft-related forensic toxicology examinations are performed either by the AFIP or the EPILAB.

Civilian reference laboratories

In certain instances, MTFs send tests to accredited civilian reference laboratories. This service is usually provided during emergency situations (e.g., down or broken instruments) or to reduce turnaround times for tests normally sent to military reference laboratories. In some cases, it may actually be less expensive to utilize civilian laboratories as opposed to shipping tests to other military facilities. MTFs ship specimens to civilian laboratories on a test-by-test basis; each such occurrence must meet the appropriate criteria predetermined by your laboratory and/or MTF. Cost, turnaround times, and laboratory accreditation are important considerations when selecting a civilian reference laboratory—or any reference laboratory for that matter. The reference lab must meet the particular requirements of your laboratory.

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) serve as the national focus for environmental health issues; health education and promotion programs; and, of course, developing and applying disease control and prevention. These activities are designed to improve the health of the people of

the United States. They provide many services that are available to international, national, state, local, and private organizations, as well as to the armed forces. Located in Atlanta, Georgia, the centers provide educational materials and different guidelines that affect the clinical laboratory.

All of the above reference laboratories help Air Force laboratories to meet the MTF mission. From this brief overview of the laboratory mission, let's move on to the attitudes you must maintain when performing this mission.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

001. The mission

1. What is the laboratory's mission, and how is it accomplished?
2. What are the various types of reference laboratories that may support your laboratory, and what are some examples?
3. What are some of the important factors to consider when selecting a civilian reference laboratory?
4. What laboratory is tasked with handling all laboratory testing involved with an aircraft accident or incident?

1-2. Patient and Professional Relationships

Legal responsibilities and ethical issues are very important to the patient (and must be to you too) and have become major public concerns in recent years. Today, patients are more educated and informed than ever before. They are aware of their rights and do not hesitate to seek legal remedies when they feel that their rights have been violated. The US government is spending millions of dollars on lawsuits because of careless health care. As a medical laboratory technician, this affects you in two ways. First, as a taxpayer, part of the money spent on lawsuits comes out of your pocket. Second, as a military member, you are subject to charges if the care you provide is substandard. Your duties and responsibilities are clearly outlined in several publications (e.g., Air Force Manual [AFMAN] 36-2108, *Airman Classification*, and the 4T0X1 Career Field Education and Training Plan [CFETP]). You can be charged with dereliction of duty under the *Uniform Code of Military Justice (UCMJ)* if you do not comply with these documents. Punishment can range from a letter of reprimand to courts-martial. Knowing and understanding ethics, related terms, ethical values, and standards of conduct that govern your job helps you avoid the consequences of providing poor care, but most importantly, helps you provide the best patient care possible.

002. Medical ethics

"What do ethics have to do with my job?" The answer is very simple—everything! Reflect on what you are doing for a moment. As a military member, you are held in the public trust; your ethical standards must be above reproach to maintain trust with the American people. In addition, as a member of the health-care community, you are in a profession that has its own complex ethics that

you must follow. Because most patients have a very brief interface with the laboratory technician for specimen collection and they have a limited understanding of what it takes to produce quality laboratory results, they usually base their opinion of care on how they feel afterwards and not on technician performance. Although patients expect to undergo strange and, sometimes painful, experiences during their hospital stay, they have no idea they are receiving poor care until something goes wrong or they experience something unexpected.

“So why should you provide good care?” The bottom line is that it is the right thing to do and, in most cases, nobody but you will ever know the quality delivered. If your ethical standards are high, the quality of care you provide will also be high. Conversely, if your standards are low, you become careless, take shortcuts, and generally provide inferior care. The intent of this lesson is to broaden your perspective regarding how you must use ethical standards to interact with patients, coworkers, and hospital staff.

Concepts and origins of ethics

Ethics is a *code of conduct* that describes actions as being either “right” or “wrong.” We frequently use the *Golden Rule* (treating others as you wish to be treated) as a basic ethical standard. However, in the medical profession, ethics are a little more complex than the Golden Rule. Therefore, each medical profession has developed a code of ethics to guide the behavior of its members. Later, we look at a medical laboratory-centered code of ethics after we lay the foundation of what ethics are.

Ethical terms

Overarching ethics in the Air Force are the core values of the service:

Integrity First	Service Before Self	Excellence
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If you apply the Air Force core values to your conduct, you can safely say that your ethics will be above reproach. Along with the changes in medical ethics came a change in the language used to describe ethical behavior. As ethics continue to change and develop, the language used to define them grows more complex. Before you can understand the codes of conduct, you must understand the many terms used within the codes.

Moral character

Moral character refers to the personality or character traits that an individual possesses; moral character we usually define as a desirable trait. Some traits considered desirable in medical professions are temperance, courage, wisdom, fortitude, faith, hope, charity, industriousness, honesty, and compassion. Before you scoff at this list, ask yourself, “Are there any traits listed above that I wouldn’t want in a person who is caring for either my child or me?” Now ask yourself, “Do I possess these traits?” If you have difficulty applying these adjectives to yourself, ask, “Is my conduct above reproach?” If you can answer yes, then you have the desired traits. Always strive to be the exemplar of these qualities, and I challenge you to continually do so.

Moral obligation

Moral obligation is a feeling or urge that compels you to behave in a certain way. Moral obligation is a result of moral character. To illustrate this, consider the performance of any laboratory test, but in this case, we must consider a differential. A technician who lacks moral obligation may only count 50 cells on a differential and multiply by two or make up results in order to finish early. However, the technician who is conscientious about his or her job and patient care performs in a manner that is always above reproach, regardless of personal needs or desires. In the second example, the patient comes first for this technician—dovetailing nicely with all three Air Force core values we discussed previously. As you can see, if you apply Air Force core values to the way you conduct business, your

ethical troubles should be nil. By applying these principles consistently, you establish a pattern of excellence.

Building blocks of moral obligation

We briefly present some of the terms and definitions that provide the foundation of moral obligation here.

Fidelity

Fidelity is the act of keeping a promise. This promise may be clearly defined or implied. Regardless of its nature, it must be upheld. Patient confidentiality is an implied promise that represents fidelity.

Nonmaleficence

Nonmaleficence is the ethical principle of doing no harm to yourself or others. Many of the tasks you do routinely are capable of harming the patient; you must take appropriate measures to avoid harming patients or coworkers.

Beneficence

Beneficence is the act of bringing about good or acting in the best interest of (as an advocate for) someone else. The whole medical profession is dedicated to acting in the patient's best interest.

Failing moral obligation

When someone fails to meet his or her moral obligation(s), there are consequences. We briefly explore some of the consequences here.

Reparation

Reparation is the act of compensating or making amends for a wrong that has been previously committed. The reparation varies with the degree of wrong that has been done. The reparation could range from an apology to monetary restitution. An example of restitution applied to the medical profession occurs when a patient is awarded damages in a medical malpractice lawsuit.

Incarceration

Incarceration means imprisonment. The Healthcare Insurance Portability and Accountability Act of 1996 (HIPAA) and other laws have "teeth" in that there are provisions for violators to be incarcerated, pay heavy fines, or both.

A delicate balance

There are many types of moral obligations. You'll discover that it is as difficult to fulfill all these obligations as it is to satisfy all members of a particular group. Ethical behavior requires a delicate balance of judgment, maturity, acceptance, and understanding. Frustrations may be frequent, but as long as you behave and perform your duties with high standards of conduct and to the best of your abilities, you will fulfill your ethical obligations.

Moral responsibility

It's not enough to act ethically; you must also be willing to accept full responsibility for your actions. Acceptance of responsibility implies that you had a choice and that you voluntarily performed the duty. Also implied is that you had the necessary skills, knowledge, and authority to perform the duty in question. If you don't have them, then you can't be held responsible for the duty. Ethical responsibility hinges on two factors. First, you have the ability to do the task, and second, you freely choose to do the task.

Ethical values

Now that you've studied ethical terms, let's further our discussion by looking at ethical values. According to DOD 5500.7-R, *Standards of Conduct*, ethics are standards by which one should act based on values. Values are core beliefs such as duty, honor, and integrity that motivate attitudes and

actions. Not all values are ethical values (integrity is an ethical value, but happiness is not). Ethical values relate to right and wrong and take precedence over nonethical values when making ethical decisions. As we mentioned previously, the core values of the Air Force overarch ethics. DOD employees must carefully consider ethical values when making decisions as part of official duties. The primary ethical values described below are from DOD 5500.7-R.

Honesty

Honesty means being truthful, straightforward, and candid.

Truthful

Truthfulness is required. Deceptions are easily, and usually, uncovered. Lies erode credibility and undermine public confidence. Untruths told for seemingly altruistic reasons (to prevent hurt feelings, to promote good will, etc.) are nonetheless resented by the recipients.

Straightforward

Straightforwardness adds frankness to truthfulness and is usually necessary to promote public confidence and to ensure effective, efficient conduct of federal government operations. Truths that are presented in such a way as to lead recipients to confusion, misinterpretation, or inaccurate conclusions are not productive. Such indirect deceptions can promote ill will and erode openness, especially when there is an expectation of frankness.

Candid

Candor is the forthright offering of unrequested information. It is necessary in accordance with the gravity of the situation and the nature of the relationships. Candor is required when a reasonable person would feel betrayed if the information were withheld. In some circumstances, silence is dishonest; yet, in other circumstances, disclosing information would be wrong and perhaps unlawful.

Integrity

Being faithful to one's convictions is part of integrity. Following principles, acting with honor, maintaining independent judgment, and performing duties with impartiality help to maintain integrity and avoid conflicts of interest and hypocrisy.

Accountability

DOD employees are required to accept responsibility for their decisions and resultant consequences. This includes avoiding even the appearance of impropriety because perceptions affect public confidence. Accountability promotes careful, well-thought-out decision making and limits thoughtless action.

Fairness

Open-mindedness and impartiality are important aspects of fairness. DOD employees must be committed to justice in the performance of their official duties. Decisions must not be arbitrary, capricious, or biased. Individuals must be treated equally and with tolerance.

Caring

Compassion is an essential element of good government. Courtesy and kindness, both to those you serve and to those you work with, help ensure that individuals are not treated solely as a means to an end. Caring for others is the counterbalance against the temptation to pursue the mission at any cost.

Respect

To treat people with dignity, to honor privacy, and to allow self-determination are critical in a government of diverse people. Lack of respect leads to a breakdown of loyalty and honesty within a government and brings chaos to the international community.

Promise keeping

No government can function for long if its commitments are not kept. DOD employees are obligated to keep their promises in order to promote trust and cooperation. Because of the importance of promise keeping, it is critical that DOD employees only make commitments within their authority.

Responsible citizenship

It is the civic duty of every citizen, and especially DOD employees, to exercise discretion. Public servants are expected to engage personal judgment in the performance of official duties within the limits of their authority so that the will of the people is respected in accordance with democratic principles. Justice must be pursued and injustice must be challenged through accepted means.

Pursuit of excellence

In public service, competence is only the starting point. DOD employees are expected to set an example of superior diligence and commitment. They are expected to strive beyond mediocrity.

Laboratory professional ethics

You can see an example of laboratory professional ethics in the Board of Registry and American Society of Clinical Pathologists (ASCP) guidelines for ethical behavior.

Recognizing that my integrity and that of my profession must be pledged to the best possible care of patients based on the reliability of my work, I will:

- Treat patients and colleagues with respect, care, and thoughtfulness.
- Perform my duties in an accurate, precise, timely, and responsible manner.
- Safeguard patient information as confidential, within the limits of the law.
- Prudently use laboratory resources.
- Advocate the delivery of quality laboratory services in a cost-effective manner.
- Work within the boundaries of laws and regulations and strive to disclose illegal or improper behavior to the appropriate authorities.
- Continue to study, apply, and advance medical laboratory knowledge and skills and share such with my colleagues, other members of the health-care community, and the public.

003. Standards of conduct and interpersonal relationships

As a medical laboratory technician, you must maintain good professional relationships with patients, coworkers, supervisors, nurses, doctors, and all other MTF personnel. In other words, you must practice the highest standard of integrity in and out of the laboratory when dealing with others. Keep



"Cutting Red Tape...
for Cutting Edge Service"

in mind that ethics are a basis for the standards of conduct and maintaining good interpersonal relationships. You must also be aware of the Air Force Medical Service's *Strategic Priorities for Customer Satisfaction*, which was developed as a Skunkworks project. This is an initiative that establishes a customer focus (internal and external) through employee empowerment that is designed to remove barriers and red tape from day to day operations and improve Air Force healthcare delivery to world-class levels. Your supervisor can provide you with more information regarding this program.

Standards of conduct

When this CDC talks about standards of laboratory conduct, it is referring to the standards that evolved into a code of ethical conduct for medical personnel and not the standards of conduct from basic training. There are several organizations that have established codes of conduct for each class of medical personnel. Although these codes differ in their wording, the basic elements are the same.

Individual care

Treating each patient as an individual means that you avoid stereotyping patients. Treating the patient as an individual also involves respecting that individual's customs and beliefs. The Air Force operates medical facilities throughout the world. You may be exposed to many customs and beliefs with which you are unaccustomed, but which still deserve your respect. Give your patient's beliefs the same respect you want for your own beliefs.

Be aware of patient concerns as they relate to their age-specific stage of development. Typically, this applies to phlebotomy; however, don't lose sight of the patient's feelings regarding the sensitivity, or perceived sensitivity, of delivering semen, stool, or occult blood specimens and the like to the laboratory, just to name a few. The following chart, although not all-inclusive, helps delineate and provokes thought regarding this information on age-specific development and laboratory concerns for the patient during all interactions.

Age-Specific Guidelines	
Life Stage	Lab Interaction and Concerns
Neonate/infant (≈ birth to 1 year)	Provide as much comfort as possible during the procedure. Venipuncture (when required may be exceedingly difficult)—do your absolute best to minimize trauma and multiple sticks. Use a syringe and smallest-bore/highest-gauge needle as appropriate.
Toddler (≈ 1 to 3 years)	Provide as much comfort as possible during the procedure. Answer any questions honestly, but with a minimum of extra explanation.
Childhood/preadolescent (≈ 3 to 12 years)	Provide as much comfort as possible during the procedure. You can provide more detailed explanations of the procedure. Patient may show more interest in the procedure and be more inquisitive as to what he or she can expect than a patient at the toddler stage.
Adolescent (≈ 12 to 19 years)	Be sensitive of patient's feelings regarding collection and delivery of specimens of an excretory and/or secretory nature.
Early adulthood (≈ 19 to 40 years)	Be sensitive to fertility studies, fertility and sexually transmitted disease (STD) results, and the delivery of stool and semen specimens.
Late adulthood (≈ 40 to 65 years)	Health concerns increase among this age group. Be sensitive to specimen delivery of stool samples and occult blood specimens.
Geriatric (≈ 65+ years)	Veins may be frail and difficult to locate and use. Syringe use may be the most appropriate method.

Human dignity

Respect for the patient's dignity is either stated or implied in all medical professional codes. You must give this respect to all patients regardless of rank, financial status, or any other consideration. Respect for dignity includes greeting and talking to patients in a respectful manner. Always avoid undue familiarity. The old saying "familiarity breeds contempt" has a lot of truth to it. "Good morning, Major Smith" or "Hello, Mrs. Jones" is more appropriate than "Whazzup!" Respect for human dignity also includes not making any crude or inappropriate remarks about patients. Any members of the medical laboratory team who conduct themselves in anything less than a professional manner have engaged in gross disrespect for human dignity. Any technician who cannot treat patients with the respect and compassion they deserve needs to look for a new line of work.

Privacy

There are two kinds of privacy: personal and physical.

Personal privacy

In many areas, the Air Force operates on a strict need-to-know basis. This means that you mustn't reveal anything about the patient or the patient's care to anyone not directly involved with providing that care. Information that seems trivial to you may be very important to the patient. Never discuss the patient in a joking or casual manner. If the patient overhears what you are saying, not only do you

lose the rapport you worked to establish, but you may be subject to disciplinary action if the patient files a formal complaint. Even if the patient cannot hear you, making disparaging or defaming comments about him or her is unprofessional; avoid it. The patient should have a reasonable expectation to trust that his or her medical information will be handled in a discreet and appropriate manner. It is your job to maintain that trust.

Physical privacy

Physical privacy deals with avoiding unnecessary exposure of the patient. This goes hand in hand with human dignity. Although patient exposure is rarely required in the laboratory, it may occasionally be necessary. For instance, a female patient may have to remove a blouse in order to have her blood drawn. If you are a male technician and this is the case, make sure that you have a female chaperone in the drawing room with you. If a female chaperone is not available, another option is to ask the patient to change into a lab coat. This option provides access to the arm for venipuncture yet limits patient exposure. Also, only expose as much of the patient's body as is absolutely necessary. Do not put yourself in a potentially embarrassing or compromising position. This could be embarrassing for you as well as the patient. Always explain what you are going to do to the patient before you start. *Never* leave a patient who is partially exposed.

Professional competence

Professional competence protects the patient from incompetent, unethical, and illegal care. You are expected to know the consequences of the care you deliver and to avoid doing anything that might harm the patient. If a nurse or doctor asks you to do something that you are not qualified to do (e.g., drawing a blood gas), simply inform that individual that you are not able, allowed, or qualified to do the task. If that person insists that you do the task anyway, inform your noncommissioned officer in charge (NCOIC), officer in charge (OIC), or pathologist immediately. You must correct any condition that threatens the patient's health or safety.

Accountability

Be accountable for your actions. This means being responsible for your accomplishments as well as your failings. Ensure that every action you take benefits the patient. Never attempt to do anything that you are not adequately trained to do or that you are not permitted to do by local policy. Before you pass on information affecting the health or safety of a patient, be sure it is correct. If there is even the slightest doubt about any part of your response, play it safe—look it up or ask for assistance from your supervisor. By being accountable, you accept responsibility for your actions, both good and bad—much like President Harry Truman and his famous quote, “The buck stops here.”

Review

The basic ethical standards of conduct just discussed were presented as guidelines for you to follow in the course of performing your daily duties as a medical laboratory technician. Ethical behavior is the cornerstone of medicine. Use the standards presented here to help develop your own personal code of conduct; then live by that code. If you do, you'll find that your work relationships, the quality of patient care you provide, and life in general will improve dramatically.

Interpersonal relationships

The following paragraphs provide some guidance in developing personal relationships with others. Basically, there will be an expansion of the concepts that you learned earlier. Your attitude and behavior are just as important to the patient's well-being as is the test you perform.

Appearance

As a professional, and as you have been trained, always present a clean, neat appearance with a clean, pressed uniform and polished shoes. Avoid fads as well as wearing excessive amounts of jewelry or cosmetics. Patients and supervisors usually form a first impression of you based on the way you look. If your hair, clothes, and fingernails are dirty and you have an offensive body odor, what kind of

impression do you think you will make? If you look sharp, generally you act sharp; this leaves a favorable impression of you with others. Just make sure that your performance equates to the same standards as your appearance!

Attitude

Maintain a positive attitude toward your patients, coworkers, and other MTF staff. Be cheerful, respectful, and professional; it's contagious. Remember, the reason you are there is to care for the patients. Show concern for all patients; make each patient feel that his or her welfare is important to you. Do not let your personal feelings toward a patient or a request interfere with the care that you provide. For example, you may feel that a STAT is not really a STAT, but you must not let that feeling interfere with the timely performance of the procedure. It is up to the doctor—not you—to decide what is STAT and what isn't. Always act in a professional manner.

Courteous

Most patients are frightened and somewhat confused. A friendly smile and reassuring word works wonders in reducing their fears. Beware of what you say and how it may affect others. Stop and entertain a scared child or pick up and hold a crying infant. Do not let the "meat market" mentality take over. Personal touches, such as the ones we just described, go a long way toward building a positive rapport with patients. Showing that you care may actually improve the patient's response to treatment. Develop the habit of referring to your patients by their proper names or titles. Your courtesy will go a long way in leaving the impression of your laboratory's professionalism with the patient.

In addition to being courteous to the patient, don't forget to extend courtesy to your coworkers. Here are a few illustrations: Show that you respect others' time by meeting project deadlines, returning messages promptly, and arriving on time to meetings. Respect boundaries and be sensitive to your coworkers' need for privacy. Knock before entering anyone's workspace, and ask whether it's a good time to talk before launching into a discussion. If a document is not yours, don't read it; deliver it. Don't inconvenience others by leaving last week's leftovers in the refrigerator, emptying the coffee without making more, leaving paper jammed in the copier, or using the last coagulation controls without reconstituting the replacements. Remember to say please and thank you, even in brief E-mail messages. If you sense a problem or have bad news to deliver, don't play phone tag—meet in person instead. Give credit where it's due by letting your boss know when you've received help on a project, and be sure to praise your colleagues on a job well done. Don't let personal issues adversely affect the work center. If necessary, discuss the issue(s) with your supervisor, someone in the chain of command, or a referral agency to work toward resolution.

Attentive

There never seems to be an end to the tasks that need to be accomplished in the laboratory. Although you have had a busy day and need a break, don't neglect waiting patients. Waiting patients watch your work habits closely, and they may complain to the commander about how long they had to wait while people took breaks. Take breaks away from public view, not around the front desk. Time after time, you go to a different office for assistance. The person in that office is often overloaded with work, just like you. Think about how you feel if that person continues on with his or her business and doesn't acknowledge your presence. It makes you angry, doesn't it? Well, your patients feel the same way when they come to the laboratory. Keep patients informed of possibly delays and provide the expected wait times; if wait times become longer, announce this as well. Although somewhat unpleasant, being attentive to the patient in this way goes a long way toward reducing patient stress.

Cooperation, loyalty, and teamwork

Cooperation is important at all levels. You need cooperation from your patients for drawing blood and collecting various other specimens. Your patients need cooperation from you in terms of reassurance, information, and providing good care. If you fail to cooperate with other members of the

medical team, the quality of patient care will suffer. Cooperation includes such things as effective communication, courtesy, and respect for others.

There are many synonyms for loyalty: fidelity, faithfulness, allegiance, devotion, and fealty. Loyalty is the bond that holds our nation and the federal government together and is the balm against dissension and conflict. It is not blind obedience or unquestioning acceptance of the status quo. Loyalty requires careful balancing among various interests, values, and institutions in the interest of harmony and cohesion. Always be loyal to your coworkers, profession, and service. Try to give encouragement and praise to your coworkers whenever possible.

Another step you can take to build teamwork and loyalty is to help your coworkers do their job. If you finish with your work ahead of someone else, pitch in and give him or her a hand. A little cooperation and teamwork will definitely help the morale in your section. Besides, you never know when you may require some help doing your job! Loyalty also means that you never publicly criticize your coworkers. Earlier, you learned that you should not tolerate an incompetent coworker. However, avoid making comments about that individual's work performance in public. Attempt to find out why your coworker's work isn't up to standards. It may be a training issue or some other easily resolved issue. If your efforts fail, talk to your supervisor or NCOIC for that individual's assistance in resolving the problem. Another display of loyalty involves supporting the medical profession as well as the Air Force whenever possible. Teaching cardiopulmonary resuscitation (CPR) or first aid to the civilian population in your area does much to increase public knowledge and support of Air Force medicine.

Another word closely related to loyalty and cooperation is "teamwork." Medical staff members must work together effectively to deliver quality health care. The doctor depends on you to provide accurate laboratory results. A patient's life may depend on how well you and other members of the team work together. Always treat your coworkers with respect and courtesy. Be professional. Avoid horseplay and idle conversation. Address team members by their rank or title and last name. Avoid using first names. Although you may be friends, being overly familiar with coworkers in front of patients detracts from your image of professionalism. As you learned before, never belittle a coworker in front of patients or other personnel. If you want to discuss a problem with someone, do it discreetly and in private. If an individual is performing in a substandard manner, you owe it to your patients to try to correct the situation. Never forget that the patient's welfare is more important than someone's hurt feelings or the possible loss of friendship.

Communication

Whether spoken or unspoken, always communicate in a friendly, respectful manner. If you are overly familiar with your patients, they may think that you have a casual attitude about their care. Address *military members*, both active and retired, *by their titles*. That is a right they have worked hard to earn. Failure to show proper respect for military members, particularly those who outrank you, is a breach of military courtesy and discipline. Adolescent patients may be more cooperative if you address them in the same way you address adults. Children usually respond better if you address them by their first name or nickname. When dealing with children and infants, get the parents involved whenever possible. Refer to the age-specific guidelines we presented earlier in the lesson. A high percentage of a patient's perception of quality health care comes from personal contact with members of the health-care team. Remember, good communication is the key to improving this perception.

Telephone etiquette

The MTF staff is influenced not only by personal contact with medical laboratory personnel but also by the presence or lack of good telephone etiquette. Here are a few rules that can help with telephone manners. Answer the phone promptly, identify yourself and your office, and speak distinctly (e.g., "Microbiology, Airman Doe, may I help you?"). If you must place a caller on hold, make every attempt to minimize the time the person remains on hold. Check back in a timely manner (ideally, less

than 1 minute) and be prepared to take a message for the current call as well as for any calls received. Ensure that all messages are delivered to the intended recipients.

Review

You have studied several ways to establish high standards of conduct, possess good interpersonal relationships, and communicate with others. By following the guidelines outlined in this text and treating people the way you want to be treated, you should have few problems establishing and maintaining good relationships with your patients and your medical colleagues.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

002. Medical ethics

1. Match the terms in column B with the statements in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

Column A

- ____ (1) Being faithful to one's convictions.
- ____ (2) Being open-minded and impartial.
- ____ (3) Only making commitments within your authority.
- ____ (4) The feeling or urge that compels you to behave in a certain way.
- ____ (5) The balm against dissension and conflict.
- ____ (6) Means being truthful, straightforward, and candid.
- ____ (7) Treating people with dignity.
- ____ (8) Avoiding even the appearance of impropriety and limits thoughtless action.
- ____ (9) Treat others as you would like others to treat you.
- ____ (10) The bond that holds nations and governments together.
- ____ (11) Usually defined in terms of desirable traits: temperance, courage, wisdom, faith, hope, charity, etc.
- ____ (12) Compassion—the essential element of good government.
- ____ (13) Fidelity, nonmaleficence, beneficence, and reparation are a part of this ethical term.
- ____ (14) Striving beyond mediocrity.

Column B

- a. Golden Rule.
- b. Hippocratic oath.
- c. Florence Nightingale.
- d. Moral character.
- e. Moral obligation.
- f. Moral responsibility.
- g. Moral policy.
- h. Honesty.
- i. Integrity.
- j. Loyalty.
- k. Accountability.
- l. Fairness.
- m. Caring.
- n. Respect.
- o. Promise keeping.
- p. Responsible citizenship.
- q. Pursuit of excellence.

003. Standards of conduct and interpersonal relationships

1. What is included in the respect for human dignity?
2. You must give proper regard to patient specimen delivery. Why?
3. What are the two kinds of privacy and how would you describe each?

4. What does professional competence do for a patient?
5. What is accountability?
6. Whom must you be loyal to?
7. What does cooperation include?
8. What two things are just as important to the patient's well-being as your technical performance?
9. How can you help reduce a patient's fears?
10. Whom do you talk to first if you are having difficulty dealing with personal problems?
11. Where do you take coffee breaks or other type breaks?
12. What are some rules that can help with telephone manners?

1-3. Files Maintenance

You may ask yourself, "Why do I need to keep records at all, especially old records?" The reason is that it is the *law*! Also, it just makes good common sense and lends itself to a well-organized office.

004. Files maintenance

The Air Force Records Management Program implements several titles from the *Code of Federal Regulations (CFR)* as well as several DOD directives. The importance of proper recordkeeping is rooted in law. To illustrate this fact, consider whether you are able to recall, from memory, everything you did a few years ago (or even a few months ago) while performing a specific procedure or the exact sequence of events in a certain situation. The likelihood is low. Documentation of records makes it possible to obtain the correct information about what you did or what happened in the past. Air Force Instruction (AFI) 33-322, *Air Force Records Management Program*, governs Air Force recordkeeping. This lesson covers the purpose and laws governing records, a definition of records, and the Records Information Management System (RIMS).

Purpose of records

Records play a vital role in managing and operating Air Force activities. They serve as the memory of the organization, a record of past events, and the basis for future actions. Records managed systematically are complete, easily accessible, and properly arranged to serve current and future management needs, which enhances effectiveness and economy of operations.

Records management personnel

While there are records management personnel at every Air Force level, you will likely be limited in your dealings with the personnel at your local base. These personnel include the following: records managers (RM), functional area records managers (FARM), chief of an office of records (COR), and records technicians (RT). Below are the descriptions of the personnel involved in records management.

- *RM*—Installation level; administers training, provides staff assistance, manages staging area; performs staff assistance visits (SAV) and/or quality assistance visits (QAV) at least every 24 months.
- *FARM*—Unit level; serves as functional area point of contact. Assists RMs and provides guidance to the CORs and RTs with file maintenance and disposition; ensures eligible records are retired promptly.
- *COR*—Typically the highest ranking person in an office and is responsible for all records under his or her control. COR duties include overseeing all records; ensuring offices create only essential records, preserving permanently valuable records and disposing of temporary records; ensuring proper training for RTs.
- *RT*—RTs are the worker bees of the office files: maintaining, servicing, and disposing of records for their office. The RT's duties include maintaining files and reviewing and evaluating special files as well as filing everyday paperwork to physical disposal of designated office records.

Definition of records

What does the Air Force consider a record? The Air Force follows the United States law. Title 44 *United States Code (USC)*, Part 3301, *Disposal of Records*, defines a record as follows:

All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by any agency of the U.S. Government under federal laws, or in connection with the transaction of public business, and preserved or appropriate for preservation by an agency, or its legitimate successor, as evidence of the organizations, functions, policies, decisions, procedures, operations, or other activities of government or because of the informational value of data in them. Library and museum material made or acquired and preserved solely for reference or exhibition purposes, extra copies of documents preserved only for convenience of reference, and stacks of publications and processed documents are not included.

New technologies and records

Records are information that you preserve and manage; they exist independent of form. Key personnel responsible for managing an office's electronic records are the RMs, FARMs, and CORs. Because records on electronic media may contain information that is of legal significance, the system integrity must be established by thoroughly documenting the system's operation and the controls imposed on it. Retain electronic records and dispose of them according to the appropriate table and rule of AFMAN 37-139, *Disposition of Air Force Records—Records Disposition Schedule*.

Laboratory working definition of records

Records come in varying forms and are not limited to paper. For laboratory purposes, let's define records as "all documents, regardless of form, used in conjunction with patient care and the

management of the laboratory.” This means that microfilm, CD-ROM, diskettes, or hard drives can also be considered records. Some records require managed care and preservation due to the nature of the information they contain (e.g., emergency disaster contingency plan, staff meeting minutes, etc.). See AFMAN 37-139 for managing requirements.

Records Information Management System

An organized filing system will bring your laboratory into compliance with the law regarding recordkeeping and using RIMS will accomplish this in short order. According to AFMAN 37-123, *Management of Records*, RIMS is the mandatory Air Force-wide information management standard automated system. It provides the tools that records managers need to automate some of their records management. It automates records management functions by providing an abbreviated, on-line database of tables and rules from AFMAN 37-139. RIMS makes it easier to (1) prepare file plans, disposition control labels, and folder labels; (2) track SAVs and training schedules of records technicians; (3) manage staged records; (4) provide backup and recovery; and (5) allow for difficult reporting. However, classified information, sensitive information, or Privacy Act material can't be included in RIMS.

If you are selected as the RT for your laboratory, you will receive extensive training regarding the use of RIMS and how to properly set up your laboratory's files plan. Just keep in mind that proper recordkeeping from cradle to grave is important and is the law.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

004. Files maintenance

1. Match the terms in column B with the statements in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

Column A

- ____ (1) Serves as the point of contact within the functional area.
- ____ (2) Worker bees of the office files: maintaining, servicing, and disposing of records for their office.
- ____ (3) They serve as the memory of the organization, a record of past events, and the basis for future actions.
- ____ (4) The mandatory Air Force-wide information management standard automated system.
- ____ (5) All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics.
- ____ (6) Administers the program within the organization or installation; performs SAVs or QAVs at least once every 24 months.
- ____ (7) Can be an officer, civilian, or enlisted person who has possession of Air Force records.

Column B

- a. Purpose of records.
- b. RM.
- c. FARM.
- d. COR.
- e. RT.
- f. Record copy.
- g. Definition of records.
- h. RIMS.
- i. Active records.
- j. Inactive records.
- k. Cutoff.
- l. Retention period.
- m. Disposition.
- n. Permanent record.
- o. Temporary record.
- p. Disposition control label.

Answers to Self-Test Questions

001

1. To meet the mission of the MTF, and this is accomplished by providing accurate, reliable, and timely services that aid in the diagnosis, treatment, and prevention of diseases affecting the health and welfare of all patients, whether they are active duty military personnel, retirees, dependents, or civilians.
2. Military and civilian; other armed services medical groups (Air Force, Army, or Navy), Institute of Environmental Safety, Occupational Health, and Risk Analysis (also known as the EPILAB), Armed Forces Institute of Pathology (AFIP), and the Centers for Disease Control and Prevention (CDC).
3. Cost, turnaround time, and laboratory accreditation of the reference laboratory.
4. The Armed Forces Institute of Pathology (AFIP).

002

1. (1) i.
(2) l.
(3) o.
(4) e.
(5) j.
(6) h.
(7) n.
(8) k.
(9) a.
(10) j.
(11) d.
(12) m.
(13) e.
(14) q.

003

1. Greeting and talking to patients in a respectful manner, avoiding undue familiarity, and not making any crude or inappropriate remarks about patients.
2. Sensitivity regarding the specimen delivery (semen, stool, urine, etc.) must be afforded to the patient. The patient most likely does not work in the medical arena where specimens of this kind are “all in a day’s work” thus making collection instruction, receipt, specimen collection, and specimen delivery difficult and potentially embarrassing for some patients. The laboratory technician’s professionalism can alleviate a large portion of the patient’s anxiety.
3. Personal and physical; personal privacy means that you shouldn’t reveal anything about the patient or his or her care to anyone not directly involved with providing that care and physical privacy deals with avoiding unnecessary exposure of the patient.
4. Protects the patient from incompetent, unethical, and illegal care.
5. This simply means being responsible for what you do or fail to do. Act within your limits of your training, and ensure that every action you take will benefit, not harm, the patient.
6. Always be loyal to your coworkers and to your profession.
7. Such things as effective communication, courtesy, and respect for others.
8. Your attitude and behavior.
9. Provide a friendly smile and a reassuring word.
10. Your supervisor.
11. Away from public view, not around the window or front desk.
12. Answer promptly, speak distinctly, identify yourself and your office, be prepared to take (and deliver) a message, be attentive, and don’t yell into the mouthpiece.

004

1. (1) c.
- (2) e.
- (3) a.
- (4) h.
- (5) g.
- (6) b.
- (7) d.

Do the unit review exercises before going to the next unit.

Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter. When you have completed all unit review exercises, transfer your answers to ECI (AFIADL) Form 34, Field Scoring Answer Sheet.

Do not return your answer sheet to AFIADL.

1. (001) In a clinical laboratory, the extent of laboratory services provided depends upon the
 - a. size of the MTF.
 - b. mission of the MTF.
 - c. base on which the MTF is located.
 - d. type of patients requiring treatment at the MTF.
2. (001) Which reference laboratory serves as the national focus for environmental health issues and health education and promotion programs?
 - a. NIH.
 - b. AFIP.
 - c. CDC.
 - d. EPILAB.
3. (002) In the medical field, which is a description of integrity?
 - a. Treating people with dignity.
 - b. Being faithful to one's convictions.
 - c. Being truthful, straightforward, and candid.
 - d. Accepting responsibility for your decisions.
4. (002) Which ethical value do we describe as "to treat people with dignity, honor privacy, and allow self-determination"?
 - a. Caring.
 - b. Respect.
 - c. Fairness.
 - d. Promise keeping.
5. (003) Due to veins that are weak and difficult to locate, it is suggested that the *most appropriate* method for venipuncture at this stage is with a syringe.
 - a. Neonate.
 - b. Toddler.
 - c. Pediatric.
 - d. Geriatric.

6. (003) Loyalty, cooperation, and working together effectively to render quality health care are part of
 - a. attitude.
 - b. teamwork.
 - c. attentiveness.
 - d. courteousness.

7. (004) Records play a vital role in managing and operating Air Force activities because they serve as
 - a. the memory of the organization, a record of past events, and the basis for future actions.
 - b. the memory of the organization, a record of past events, and reveal the basic organizational structure.
 - c. the backbone of training information, a record of past events, and the basis for future actions.
 - d. the backbone of training information, the memory of the organization, and the basis for future actions.

8. (004) Who is responsible for maintaining, servicing, and disposing of records for their office?
 - a. RMs.
 - b. RTs.
 - c. COR.
 - d. FARMs.

Please read the unit menu for unit 2 and continue. ➔

Unit 2. Laboratory Quality Assurance

005. Quality assurance.....	2-1
006. Purpose and content of operating instructions.....	2-15

QUALITY, whether inferior or superior, affects our daily lives. Here are a few definitions from *Webster's II New Riverside University Dictionary* on quality: "An attribute, a character trait, or degree or grade of excellence." *Webster's* also defines quality control as "a system for maintaining proper standards in manufactured goods, especially by regular inspection of the product." Keep in mind that the laboratory does produce a product—patient results. Different references use different names for the quality system described (e.g., quality management, quality assurance, quality approach, quality improvement, and so on). Different terminology for the elements and processes of the quality system was used, but the goal was always the same—produce a quality product. Therefore, we have used what we feel to be the best terms. Hopefully, you will understand the information, even if you are not accustomed to the terminology used here.

005. Quality assurance

Quality assurance (QA) is a program intended to monitor all steps and methods utilized to produce accurate and reliable results. This includes components of quality control (QC), as well as overall laboratory management. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines quality assurance as "a well-defined, organized program designed to enhance patient care through the ongoing objective assessment of important aspects of patient care and the correction of identified problems." Thus, QA monitors the entire process of patient care. Also, QA only works if everyone in the laboratory takes responsibility for the program. Keep in mind that the QA program may be a little different in each laboratory discipline. A case in point, the blood bank or transfusion service must have a medical director, who is a licensed physician and is qualified by training and/or by experience. This individual has responsibility and authority for all medical and technical policies and procedures outlined in AFMAN 41-111, *Standards for Blood Banks and Transfusion Services*.

NOTE: A meaningful QA program must be able to monitor both quality control and other laboratory activities. All laboratory activities can basically be divided into two categories: nonanalytic control and analytic quality control.

Nonanalytic control

Nonanalytic control encompasses all activities not directly associated with the performance of the clinical assay itself. This includes both preanalytical and postanalytical activities.

Preanalytical

Preanalytical activities are ordering tests; ensuring correct patient identification and preparation; specimen collection, transport, identification, and accessing; and specimen processing for analysis. Preanalytical activities are, at times, out of the laboratory's control (e.g., a blood sample drawn and transported to the laboratory by other hospital personnel). Because improper fasting or ignoring special instructions can affect patient results, it is important to have up-to-date laboratory guides available for clinics and wards to help guarantee quality specimens; this is within the laboratory's control. Also, whether the specimen is acquired in the lab, clinic, or ward, correct patient identification is essential and must always be verified.

Postanalytical

Postanalytical activities are validating results, reporting results, workload recording or test charging, and storing specimens. During postanalytical activities, especially when reporting results, clerical errors often occur. Clerical errors can be hard to monitor and difficult to detect. One way of avoiding

this type of errors is to constantly double-check patient identification, specimen numbers, and test results. Test result errors can occur when certifying results transmitted from the instrument to the CHCS, entering results by keyboard, or handwriting results. Paying attention to detail is always critical when reporting laboratory results. Remember, the physician treats the patient based upon his or her interpretation of the laboratory's results. Clerical and human errors cannot be totally eliminated, but awareness can decrease these errors.

Analytic quality control

There are two kinds of analytic QC programs—*internal* and *external*. Internal QC programs use controls that are usually commercially prepared, prepared “in-house,” or a combination of both. Internal QC programs are done on a day-to-day basis to monitor normal analytical performance. We discuss external QC programs a little later. For our purposes, we define analytic QC as a control procedure that monitors analytical performance to ensure consistently accurate and precise results have been provided. The International Committee for Standardization in Hematology (ICSH) defines *accuracy* as “an agreement between the best estimate of a quantity and its true value.” *Precision* is the reproducibility or the variation of repeat measurements of the same analyte. The reliability of each measurement performed on a patient sample will result in sound medical decisions. This will give the patient the best medical treatment possible. A primary function of QC is to identify unsatisfactory equipment and/or instrument performance through preventive maintenance; method validation; use of standards, calibrators, high and low controls, and control review; and by documentation. By monitoring QC, we can detect and identify shifts, trends, and false results. In turn, we can use this information to correct procedural or instrumental problems. This lesson cannot possibly encompass all there is to know about analytic quality control; consequently, this will be a brief introduction. For more information, consult this volume's bibliography for references.

Parts of a wheel

Often, QC problems aren't due to large obvious factors but small, not-so-obvious ones. It is for this reason, when a problem arises, you always check the basics first. We can illustrate analytical quality control by using the spokes of a wheel, as shown in figure 2-1. If one of these “spokes” is bad or inferior, then the wheel becomes weak and can be easily broken. Think of a laboratory result as the wheel upon which the physician and the patient rest. If the wheel is weak or broken, what happens? The physician uses incorrect information to diagnose and then treat his or her patient. The patient cannot function as he or she should and can possibly break or die. Therefore, those areas involved in QC represent a spoke on the wheel.

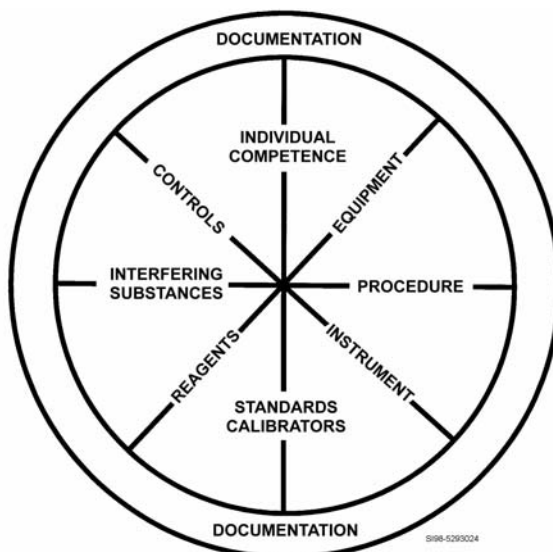


Figure 2-1. An illustration of the quality control wheel.

NOTE: Documentation is the “covering” of the wheel and is involved with all the spokes.

Individual competence

Major issues concerning individual competence were presented earlier, thus we won't repeat them here. However, individual competence influences preanalytical activities, postanalytical activities, as well as analytical quality control. This area is so important within the laboratory arena that requirements for competence folders (on-the-job training [OJT] records) have been established. These folders are inspected by various accreditation agencies. In-services can be used to maintain and update personnel on new procedures and are documented in the competence folder.

Equipment

Accuracy of results also depends on properly functioning equipment. All pieces of equipment involved in producing results must be properly maintained and monitored. The College of American Pathologists (CAP) publishes a *Laboratory Instrument Verification and Maintenance Manual*, which includes information on requirements, regulations, and standards of CAP, JCAHO, and National Committee for Clinical Laboratory Standards (NCCLS). Sample forms for documentation, frequency, and type of maintenance for all laboratory equipment are presented in this publication. Listed below are different pieces of equipment and brief guidelines for maintaining this equipment. Remember to follow your laboratory's equipment maintenance operating instructions (OI) and documentation procedures for all preventive maintenance.

Glassware and plasticware

Believe it or not, glassware has different properties based on the type of silicate anion in its structure and its cation content. The brand or type of laboratory glassware used by your laboratory depends upon its purpose and its characteristics (e.g., thermal durability; alkali, zinc, or heavy metal content; chemical stability; electrical characteristics; corrosion resistance, optical qualities; and color—for light-sensitive materials). For instance, organic contaminants found in soft glass and borosilicate glass disposable pipettes can interfere with analytical procedures using ultraviolet (UV) absorption or fluorescence techniques. Also, some disposable pipettes may release alkali into the pipetted liquid and cause considerable errors in certain critical assay procedures (such as trace metal analyses). Plasticware has greatly enhanced specific laboratory analyses that require high corrosion resistance and high impact or tension strength. Remember, you must also consider chemical content (polyethylene, polypropylene, fluorocarbon resins, etc.) when performing certain laboratory procedures. Cleanliness of glassware and plasticware is very important. Immediately after you use them, rinse glassware and plasticware with a weak solution of detergent until all surfaces are thoroughly washed. Follow the manufacturer's directions when using an automatic washer and dryer. For manual hand washing of glassware and plasticware, use a metal-free, nonionic, low-alkaline detergent. If needed, you can detect leftover or residual detergent by measuring the pH (potential of hydrogen) of water added to the glassware or through acid-base indicators.

Pipettes

Pipettes can be manual, semiautomated, or automated. Two types of manual pipettes are transfer and measuring. Transfer pipettes (volumetric and Ostwald-Folin) are designed to deliver a fixed volume of liquid. The measuring pipettes (Mohr and serological) are graduated or etched with marks to deliver different amounts of liquid. Mohr pipettes are not etched to the tip and require controlled delivery. On the other hand, the serological pipette is etched to the tip and, therefore, must be blown out. If the glass is etched with a ring at the top of the pipette, it must be blown out. Verification of pipette calibration must be done and can be performed using water and the gravimetric method (see a chemistry reference book for the procedure). Micropipettes (measuring 1 to 500 microliters [μ l]), semiautomatic pipettes, dispensers, and diluters must also be checked for accurate calibration. These pipettes can be calibrated using the gravimetric method or a spectrophotometric technique. See the manufacturer's instructions for the recommended method and your laboratory's OI for the procedure.

and calibration schedule (annually, semiannually, or quarterly). The calibration schedule may depend on the type of testing and procedures accomplished in your laboratory.

Balances

There are two types of balances: double-pan and single-pan. Double-pan balances consist of a single beam with arms of equal length with a pan attached to each arm. The single-pan balance has arms that are unequal in length. Balances are in the classic form (beam poised on an agate knife-edge fulcrum) or modern form (mechanical or electronic), which apply the principle of equilibrium in a variety of ways. Place all balances in a vibration-free area and away from strong air current. Use analytical weights to verify the performance of both single- and double-pan balances. The National Institute of Standards and Technology (NIST) recognizes five classes of analytical weights, as shown in the table below.

Class	Description
M	Class M weights are of primary standard quality and are used only to calibrate other weights.
S	Class S weights are used for calibrating balances and range from 100 grams (g) to 1 milligram (mg).
S-1	These weights have greater tolerance than class S weights. They are used for routine analytical work (counterbalance for direct comparison weight) and range from 100 g to 1 mg.
P	These weights have greater tolerance than class S-1. Weights range from 100 g to 1 mg.
J	Class J weights are intended for microanalytical work and range from 50 mg to 0.05 mg.

Thermometers

The two most prevalent types of thermometers are the liquid-in-glass and thermistor probes. The accuracy of, and agreement among, all thermometers used to monitor laboratory equipment must be verified. Before being put into use, and annually, each thermometer must be calibrated against a NIST certified thermometer. Details of the verification of calibration can be found in NCCLS 12-A2, *Temperature Calibration of Water Baths, Instruments, and Temperature Sensors; Approved Guideline*.

Incubators/CO₂ incubators

Incubators must be kept clean and their temperature and/or carbon dioxide (CO₂) level monitored and recorded daily. Some of the older models may require a water pan to maintain the proper level of humidity. Check with the manufacturer's instructions for additional required preventive maintenance.

Water baths/heat blocks

Check and record the temperature of each unit on the day of use. The water should be free of debris and microscopic organisms. This can be accomplished by regularly replacing the water. Heat blocks may contain hot or cold spots not detected by a permanently mounted thermometer. Check all wells by rotating a thermometer from well to well. Areas that are either too hot or cold may be marked and avoided; preferably, you repair or replace the unit.

Refrigerators/freezers

On a daily basis, check each piece of temperature-regulated equipment for proper function and record the temperature. All temperature values out of the set range must be investigated and explained in writing. If the equipment utilizes automatic temperature recording charts, make sure they are working properly. Temperature charts from 7-day mechanical recording devices must be changed weekly, dated inclusively, and labeled for proper identification of the refrigerator or freezer. Explain any temperature variation from the desired range in writing on the chart beside the tracing; but if the

tracing is habitually a perfect circle, closely check the recorder for possible malfunction. The person responsible for changing the charts signs or initials and files the chart as a permanent record. In blood banking, refrigerators and freezers must be equipped with a recorder for continuous temperature monitoring, and they must have an audible alarm that sounds at a temperature that allows time for appropriate action to be taken before stored components reach undesired temperatures. OIs must include information on procedures for equipment failures or refrigerator and/or freezer alarms, especially after normal duty hours. Instructions must include the telephone number of the medical equipment repair technician on call and, if necessary, the location of alternate storage in the case of equipment failure.

Centrifuges

Centrifuges can be divided into three basic types: horizontal-head or swinging-bucket, angle-head or fixed-angle, and ultracentrifuge. They can be floor or desktop models with or without refrigeration. All centrifuges should be calibrated when purchased and immediately after adjustment or repair. Periodic monitoring, every 3 months, may be done by checking the speed of the centrifuge by a stroboscopic light or a vibrating-reed external tachometer of known accuracy. Check the accuracy of the timer using a reference timer (stopwatch). If the centrifuge is refrigerated, then measure the temperature monthly to be sure it is within 2°C of the expected temperature. Make all observations part of the QC record and mark the optimum speed and time of centrifugation on each unit.

Procedure or method

Policies and procedures must be clearly stated in the OI. Keep all methods up-to-date and evaluate them periodically. You must adhere to established methods and techniques described in the OIs and/or manufacturer's product insert. We discuss the purpose and content of OIs later. Research new methods thoroughly before implementation. After January 1996, all new procedures also require method validation to verify linearity. Furthermore, a method validation is performed with major reagent changes, major part replacements, and if indicated by QC problems. (Commercial kits may be available for these checks.) Analytical methods are also different and NCCLS document NRSL8-A, *Terminology and Definitions for Use in NCCLS Documents—Third Edition; Approved Standard*, has purposed the following definitions for the class of methods.

Method	Definition
Definitive method	An analytical method that has been subjected to thorough investigation and evaluation for sources of inaccuracy, including nonspecificity. These methods are related to some absolute physical quantity, such as mass. Another example is the addition of a known amount of an isotope-labeled analyte to a sample for characterization by mass spectroscopy.
Reference method	A thoroughly investigated method in which exact and clear descriptions of the necessary conditions and procedures are given for the accurate determination of one or more property values; the documented accuracy and precision of the method are commensurate with the method's use for assessing the accuracy of other methods for measuring the same property values, or for assigning reference method values to reference materials. Results of a reference method are traceable to those of a definitive method.
Designated comparison method	A fully specified method(s) that, in the absence of a National Reference System for Clinical Laboratories (NRSL)-credentialed reference method, serves as the common basis for the comparison of "field" reference materials and methods, and for the development of principal assigned values (PAV) or principal assigned characteristics (PAC).

Reference ranges

Each laboratory must establish its own reference range (old term is "normal range") for all tests performed. Labs do this when the tests are introduced or modified. A statistical study design is produced before specimens or data are collected. Specimens are drawn from a variety of demographic

factors such as sex, age, and race. At least 40 subjects should be used, but only 5 to 10 samples are drawn and tested per day. The measurements or analyses are to be performed by different technicians to avoid an erroneous (tight) reference range.

Instrument

Check instruments for cleanliness, condition of electrical elements, and stability of electrical current, and document the temperature of refrigerated or heated analyzer compartments on a daily basis. There are, of course, analyzer- or instrument-specific QC checks that are accomplished as indicated by the manufacturer. We suggest you read the product insert and technical manual for each reagent, kit, or instrument you use. Don't rely on others for QC information—read it for yourself! Also document and maintain routine instrument maintenance and troubleshooting procedures. Be sure the documentation includes the following information for troubleshooting instruments or equipment:

- Record detailed information on the nature and frequency of the problem.
- Always record the exact sequence of events.
- Identify instrumentation parameters, the cycle, or area involved.
- Record all corrective actions performed.

Reference materials, standards, and calibrators

The International Union of Pure and Applied Chemistry (IUPAC) has proposed 99.98% purity for *primary reference materials*. Unfortunately, this is not achievable for most clinical laboratory reference materials (standards and calibrators). These primary reference materials are highly purified chemicals with a definite composition that can be directly measured or weighed out for the preparation of a solution with a specific concentration. Primary reference materials are supplied with a certificate of analysis for each lot. *Secondary reference materials* cannot be weighed out, but their concentration is determined by an acceptable reference method that used a primary reference material to calibrate the method. NCCLS Standard *Terminology and Definitions for use in NCCLS Documents—Third Edition* has purposed the following definitions for reference materials.

Reference Material	Definition
Reference materials (RM)	A material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
Certified reference material (CRM)	Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure that establishes tractability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.
Standard	Something considered by an authority or by general consent as a basis of comparison or a material against which other materials can be compared.
Reference standard	A standard, generally having the highest meteorological quality available at a given location or in a given organization, from which measurements are derived.
Primary standard	A standard that is designated or widely acknowledged as having the highest meteorological qualities and whose value is accepted without reference to other standards of the same quantity.
Secondary standard	A standard whose value is assigned by comparison with a primary standard of the same quantity.
Tertiary standard	A material, the analyte concentration of which has been value assigned by reference to a secondary standard.
Working standard	A standard that is used routinely to calibrate or check material measures (values), measuring instruments, or reference materials. (A working

Reference Material	Definition
	standard is usually compared with a reference standard.)
Calibration material or calibrator	A material or device of known or assigned quantitative and/or assigned qualitative characteristics (e.g., concentration, activity, intensity, and reactivity) used to calibrate, graduate, or adjust a measurement procedure or to compare the response obtained with the response of a test specimen and/or samples.
Secondary calibrator	A substance or device that is based on a reference preparation, or in which the analyte concentration or other quantity has been determined by a formal analytical procedure of stated reliability.
Control material (CM)	A device, solution, lyophilized preparation, or pool of collected human or animal specimen, or artificially derived material, intended for use in the quality control process (and is not used for calibration purposes in the same process in which they are used as controls).

The IUPAC has established criteria for primary standards. *Certified reference standards* are well-characterized (both chemically and physically) materials with a certificate that states the results of the characterization. These standards may, in turn, be used to characterize other materials. NIST has a number of standard reference materials (SRM), and CAP has certified reference materials commercially available. NCCLS publishes the *Guidelines for the Development of Certified Reference Materials for the Clinical Laboratory* for further information.

Reagents

Laboratory chemicals, including water, come in different purity grades. The classification “reagent grade chemical” is an unofficial description because there is no agreement between chemical manufacturers concerning the designation of the various degrees of purity. However, chemicals that meet specifications of the American Chemical Society (ACS) are described as reagent or analytical reagent grade. ACS publishes *Reagent Chemicals*, a document listing these specifications. Only the chemicals that meet the specifications have the ACS label. ACS chemicals are of very high purity and are recommended for quantitative or qualitative analyses.

Purity designations

NCCLS specifications for reagent grade water are based upon microbiology content (colony forming units per milliliter [CFU/ml]), pH, resistivity, silicate level, presence of particulate matter, and presence of organic substances. Let’s look at the types of water and grades of reagents in the following table.

Purity Designation	Use or Description
Type I water	Used in test methods requiring minimal interference and maximum precision and accuracy.
Type II water	Used for general laboratory testing not requiring Type I water.
Type III water	Used for glassware washing.
Reagent grade	Certified to contain impurities below levels established by the Committee on Analytical Reagents of the ACS.
USP grade and NF grade	Meets standards established by the United States Pharmacopoeia (USP) or National Formulary (NF) but they may contain impurities that have not been identified or tested for. Pharmaceutical chemists routinely use these.
Practical grade (also known as commercial, technical, and purified grade)	Contains some impurities but are usually adequate for most organic preparations. However, they should not be used in clinical chemical analysis without prior purification.
Chromatographic grade	Minimum purity of greater than 99% as determined by gas chromatography, no single impurity exceeding 0.2%.
Spectroscopic grade	Spectrally pure in the visible, ultraviolet, and near- and mid-infrared ranges.
Ultrapure reagents	Are required for gas chromatography, high-performance liquid

Purity Designation	Use or Description
	chromatography (HPLC), fluorometry, and trace metal analyses and are termed "Spectrograde," "Nanograde," and "HPLC pure."

Reagent control

Before any degree of reliability of test results can be obtained, reagents must be monitored for quality and dependability. While regulation and licensing of commercial reagents by the Food and Drug Administration (FDA) Bureau of Biologics help to ensure initial integrity, it is the responsibility of each laboratory to verify the quality of such licensed products. Since the FDA has no jurisdiction over the condition under which reagents are delivered to the laboratory, QC verification is your responsibility. The QC records must contain the date of testing; lot number and expiration date; expected results; actual results obtained; and identification of personnel performing the procedures. Remember to annotate the date the reagent or kit is opened with initials and the new expiration date if needed. Always discard outdated reagents and kits.

Interfering substances

In this area, we examine the NCCLS term "interferent." Interferents are components of samples, other than the analyte, that alter the final result and, in turn, affect the accuracy of the analytical method. Interferents may come from endogenous or exogenous sources and may be produced in vivo, administered to the patient, self-administered, or due to sample contamination. Interferents can cause physical, chemical, or water displacement effects and/or nonspecificity. Some common interfering substances encountered in the laboratory are dietary components; preservatives and dyes; improper anticoagulants; certain therapeutic drugs; hemolysis or lipemia; presence of other body fluids; icteric specimens; bacterial contamination; and physical contaminants such as hand creams, disinfectants, or hand soaps. It is impossible to list all of the interfering substances in this CDC. Hence, read manufacturers' product inserts and instrument technical manuals for interfering substances related to each procedure.

Control materials

Controls are used to monitor the analytical performance of calibration, reagents, and instruments. Controls are performed on every analytical run. There are many kinds of controls that are commercially available. However, before you purchase a control, there are several desirable characteristics you must consider. They are cost, low vial-to-vial variance, ready to use or minimal preparation, stable after opening (for time of intended use), and stable storage for extended periods of time (unopened). Also include matrix of the control to mimic patient samples as closely as possible, be sure concentration of the analytes is high enough to monitor the analytical process, and make sure that you can purchase the control in large quantities (enough for at least 1 year).

The three basic kinds of controls are frozen pooled, patient specimens (prepared in-house); commercial lyophilized pool material; and commercial stabilized low-temperature liquid serum pools. Each type of control has advantages and disadvantages. The type of control that the laboratory uses is determined at each individual site based upon availability, analyzers used, methodologies, cost, and type of QC program that is being implemented. Of the three kinds of controls, the low-temperature liquid serum pools have the least variance of analyte between vials. Usually, controls are available in three different value levels: low, medium, and high. Purchase controls in large enough quantities to last approximately 1 year. This way you maintain the same lot numbers and lessen the amount of times you must perform your control verification procedure due to a lot number change.

NCCLS recommends the use of *matrix*-type controls. A matrix control has a composition similar to or identical with the material being analyzed. These matrix controls should mimic the unknown specimen as closely as possible. For example, when the procedure requires whole blood, then a whole blood control is used; when serum or plasma is required, then the control should be serum or plasma.

Whether the control is matrix or nonmatrix, there is one other consideration. You need to determine if you should use an *assayed* or *unassayed* control.

Assayed

Assayed materials have a specific range with a known mean. These controls include a list of values for the analytes in the control. The list, provided by the manufacturer, includes the mean (average of the test values) and standard deviation (SD—range or distribution of values about the mean) of the control for various methods and analyzers. Even though the mean and SD are given, always evaluate the control based upon the methods used in your laboratory. The main disadvantage with assayed controls is cost; they are expensive. This is due to the amount of preparation that goes into the development of the control by the manufacturer.

Unassayed

Unassayed controls are usually pooled material with a matrix similar to the patient sample. However, each laboratory must establish its range for each control. The advantage of unassayed controls is that they are relatively inexpensive.

Lot-to-lot correlations

Perform lot-to-lot correlation of controls. This means that the new control lot is run with the old control lot until the new lot's target value is established. The laboratory's target values don't have to match the manufacturer's mean values. However, if the values are outside the manufacturer's suggested ranges, either the new lot has deteriorated, the control bottle is mislabeled, or the instrument is malfunctioning. Notify the manufacturer and do not use that lot number until the problem is resolved.

Number and placement of controls

The Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) states that you must run two levels of control each 24 hours. This is the minimum number and time frame for running controls. NCCLS recommends you run at least one matrix-type control for each analytical run. However, your laboratory may run more or use more than one type of control. This increases interpretation of analytical error. Make sure the number of controls is sufficient to monitor the full range of values you are likely to encounter with the analysis of patient samples.

Another important consideration of your QC samples is placement. There are two basic types of placement methods—*random* and *fixed*. Random placement, the preferred method, spreads controls throughout the analytical run. This yields a more valid estimate of analytical imprecision. In certain instances, manufacturers may specify control placement; justification will be in the manufacturer's technical manual. Fixed placement is exactly that—fixed. Controls are set up in certain locations determined by the manufacturer or the laboratory's QC program. The main purpose of fixed-type placement is to assess system drift.

Standard deviation

Each procedure you perform is subject to error due to mechanical, procedural, or technical difficulties. The use of controls greatly adds to your ability to detect these errors. Standard deviation is an expression we use to describe the permissible range into which a control must fall to be considered in control. Should the control be outside these limits or range, the reason must be identified, explained, and annotated. *Range* is the difference between the smallest and largest values in a data group. *Standard deviation* is the square root of the variance, as shown in figure 2-2. The *variance* is the sum of the squared deviation of each observation from the mean divided by the number of observations minus 1, as in figure 2-3. *Mean* is the average value of a group of measurements; see figure 2-4 for the equation. When the SD is used in conjunction with the mean, the shape of the normal distribution curve is completely defined. When plotting the observations, 68% of the values fall within ± 1 SD, 95% of the values fall within ± 2 SD, and 99.7% of the values

fall within ± 3 SD, as shown in figure 2-5. Any value outside of ± 3 SD is statistically unacceptable. If the procedure is performed correctly and is in control, the values should be within ± 3 SD. *Coefficient of variation* (CV) is calculated as the SD divided by the mean and expressed as a percentage as in the equation shown in figure 2-6. The CV gives a more understandable picture of the deviation regardless of the nature of the measurement.

$$SD = \sqrt{\frac{\sum (\bar{x} - x_i)^2}{n - 1}} \text{ or } SD = \sqrt{\frac{\sum d^2}{n - 1}}$$

d = difference of \bar{x} and x_i

STANDARD DEVIATION EQUATION

SI965324008

Figure 2-2. Standard deviation equation.

$$SD^2 = \frac{\sum (\bar{x} - x_i)^2}{n - 1}$$

$SD^2 =$ variance

VARIANCE EQUATION

SI965324010

Figure 2-3. Variance equation.

$$\bar{x} = \frac{\sum x_i}{n}$$

\bar{x} = mean
 x_i = individual observation
 \sum = sum of
 n = number of observations

MEAN EQUATION

Figure 2-4. Mean equation.

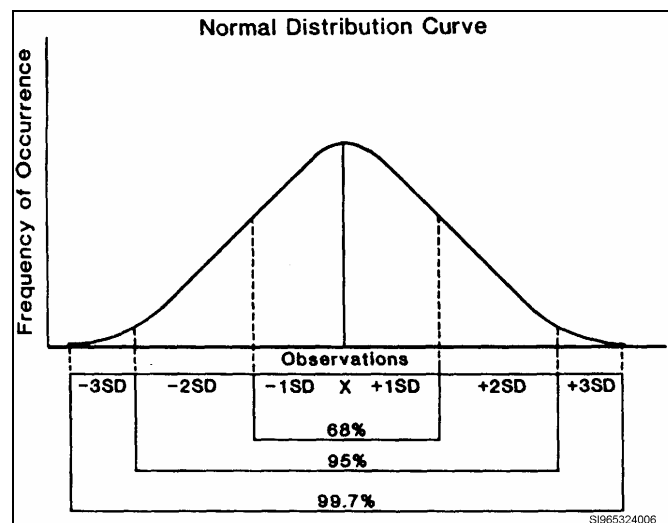


Figure 2-5. Gaussian curve.

$$\% CV = \frac{SD}{\bar{x}} \times 100 \text{ or } CV = \frac{SD}{\bar{x}} \times 100\%$$

COEFFICIENT OF VARIATION EQUATION

SI965324009

Figure 2-6. Coefficient of variation equation.

Control charts

Today, most multiparameter instruments include computer programs that automatically store and chart control results. However, if an instrument does not have its own QC program, you must manually plot the control data. Control charts exhibit and help identify problems with controls. Levey-Jennings charts, Youden plots, and cumulative sum charts are examples of ways to annotate control material (figs. 2-7, 2-8, and 2-9, respectively).

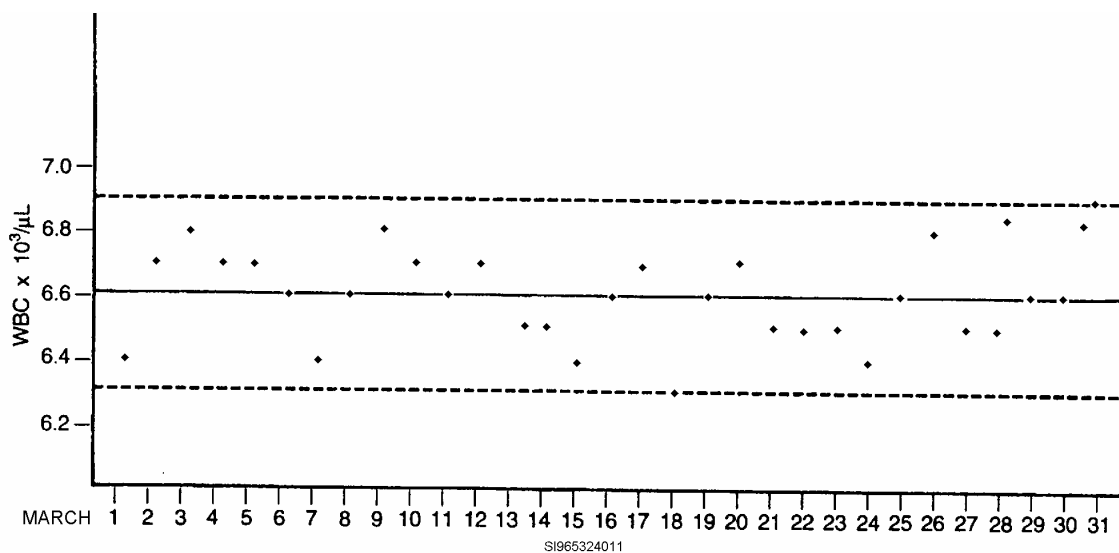


Figure 2-7. Example of a Levey-Jennings chart.

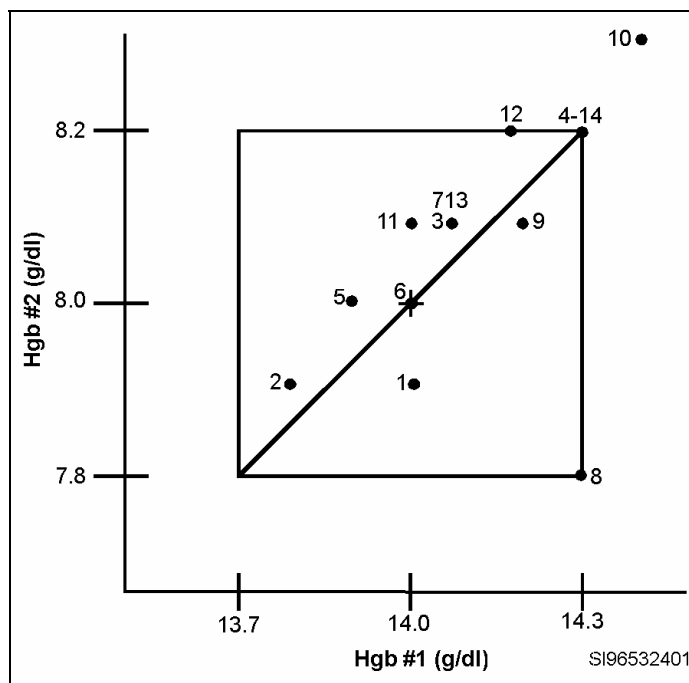


Figure 2-8. Example of a Youden plot chart.

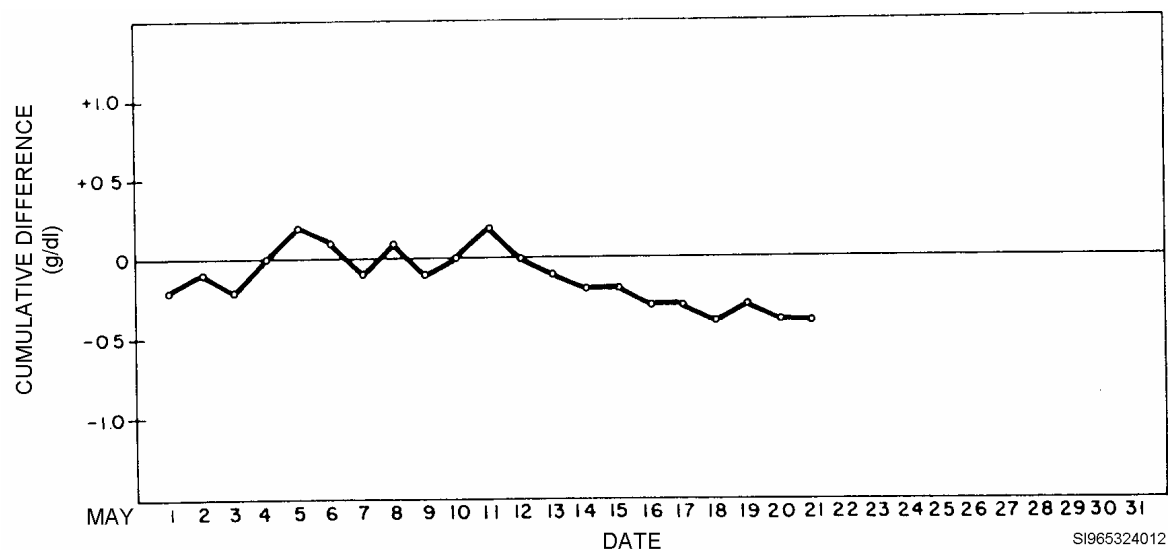


Figure 2-9. Example of a cumulative sum chart.

Errors

An error is a deviation from the truth or from an accepted expected true or reference value. There are different types of errors: systematic and random. *Systematic errors* may be due to deteriorating reagents or improper instrument calibration. They affect all results within the run or batch and can usually be detected by testing control specimens. A systematic error introduces a bias (change of mean) into a procedure and is shown in figure 2-10. Compare this curve with a curve from a stable analytical procedure, shown in figure 2-11. *Random errors* are the result of chance, they normally do not affect an entire run or batch of samples, and they may *not* be detected by testing control specimens. Random errors introduce increased variability into a procedure as shown in figure 2-12.

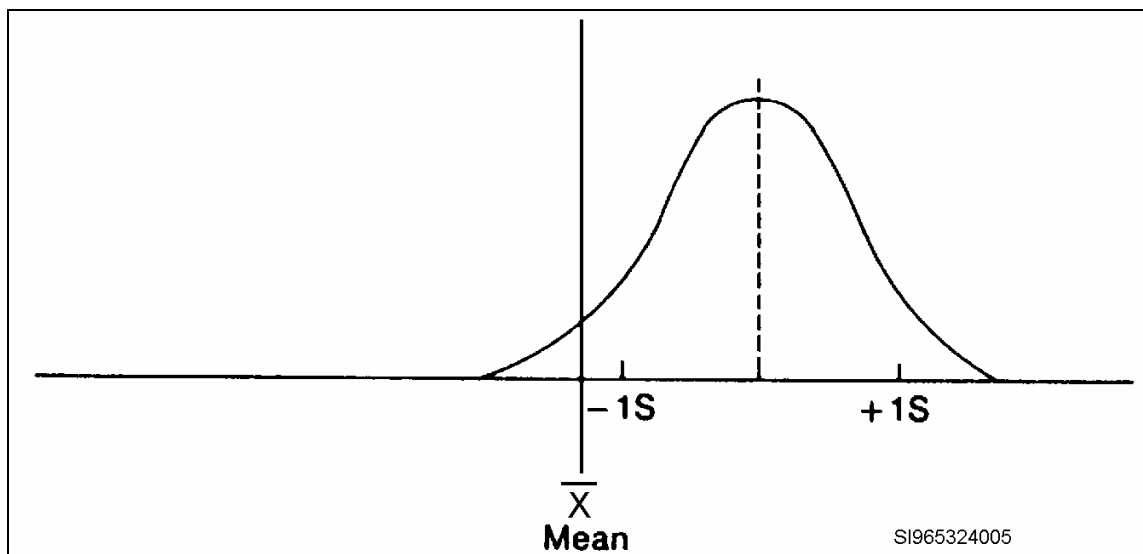


Figure 2-10. An example of a change in mean due to systemic error.

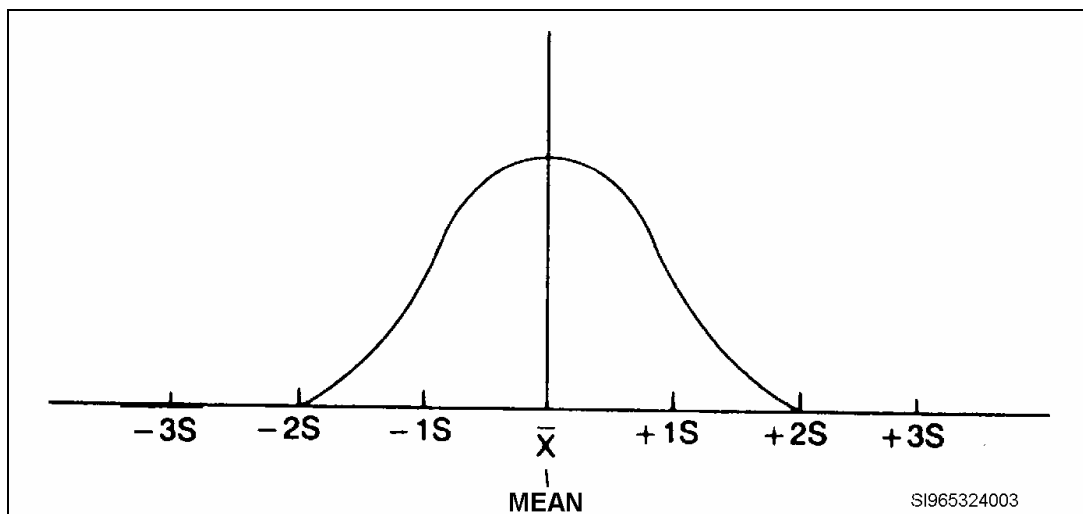


Figure 2-11. Stable procedure with a normal bell-shaped curve.

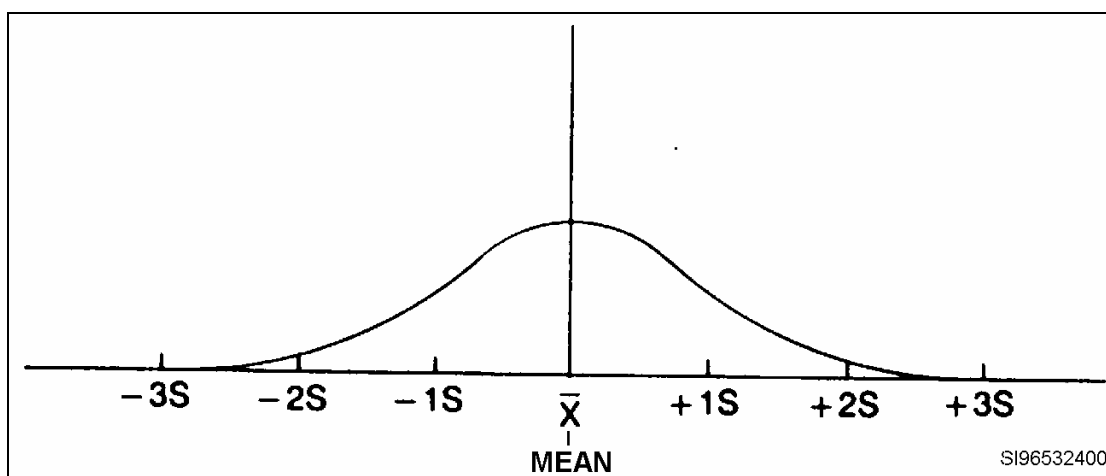


Figure 2-12. An example of a random error curve.

Trends

A trend is a series of control values that continue to move in the same direction (increase or decrease) over a period of time. They may be radical and easy to spot or develop over a period of days or weeks. The mean value will be seen to rise or fall continually, while the control values may still be within acceptable limits. Plotting control results makes the identification of trends much simpler. Trends are usually due to the deterioration of standards, controls, or instrumentation.

Shifts

The term “shifts” implies that there has been a shift in the mean value for a given control. Whereas the previous control was giving the characteristic random distribution of values on both sides of the mean, all results now appear on one side or the other. The mean has actually moved or shifted, and now the values appear scattered accordingly around the new mean. Shifts demand immediate attention.

Westgard multirules

Westgard multirules are used to determine the acceptability of an analytical run. These rules are designed to detect inappropriate bias or imprecision that may change the quality of the specimen result. James O. Westgard, PhD, and associates developed them. The multirule method is the selected method in clinical chemistry and has a high level of error detection and a low level of false rejection.

Multirules are applied before any patient data is reported. In most instances, however, they are used mainly for monitoring controls. To initiate these rules, the mean and SD must be calculated on the laboratory's controls. *Do not* rely on package inserts to acquire the mean and SD. Listed below are the Westgard multirules:

Multirules	Definition
1 _{2s}	[1 control observation exceeding the mean $\pm 2s$] is used only as a "warning" rule that initiates testing of the control data by the other control rules. An example of this rule violation could indicate a possible instrument or method malfunction.
1 _{3s}	[1 control observation exceeding the mean $\pm 3s$] is a rejection rule. An example of this rule would indicate a possible random error.
2 _{2s}	[2 consecutive control observations exceeding the same mean $+2s$ or mean $-2s$ limit] is a rejection rule. This rule can be applied either within the same control run involving both levels of control exceeding either the same $+2s$ or $-2s$ limit or include two consecutive analyses of the same control material exceeding the same $2s$ limit. An example of this rule would indicate a possible systematic error.
R _{4s}	[1 observation exceeding the mean $+2s$ and another exceeding the mean $-2s$ or more than $4s$ apart] is a rejection rule. An example of this rule indicates possible random error.
4 _{1s}	[4 consecutive observations exceeding the mean $+1s$ or the mean $-1s$] is a rejection rule sensitive to systematic error. This may occur within and across control materials. An example of this rule would indicate a possible shift or trend in the analytical process.
10 _x	[10 consecutive control observations falling on one side of the mean] is a rejection rule that is sensitive to systematic error. This rule is most commonly violated when reagent lot numbers are changed or routine calibration is performed.

NOTE: See your laboratory's OI for the usage of the Westgard multirules and how they apply to your laboratory.

Six sigma

Six sigma is a concept developed by the Motorola Corporation in the 1980s and was implemented with great success at General Electric in the 1990s and is also known as zero-defect management. Six sigma is defined as 3.4 defects per million opportunities or 99.99966% error free (0.00034% error rate). For comparison, the error rate at five sigma is 230 errors per million opportunities. Six sigma modifies the Shewhart cycle with which you are probably familiar (plan-do-study-act [PDSA]) with what is called DMAIC (define, measure, analyze, improve, and control). Six sigma concepts are crossing over from the business world into the health-care world.

Documentation

I'm sure you have heard the saying, "If it isn't documented, it wasn't done." Documentation may be the single most important component of a good QC program. Each laboratory service must have a system of recordkeeping, manual or computerized, or a combination thereof. Procedures and policies for each part of the system must be established, documented, and followed. Records must be complete, retrievable in a reasonable period of time, preserved, and protected from accidental or unauthorized destruction or modification. A system to ensure confidentiality of patient records must also be established and followed.



External quality control

All USAF medical laboratories must attain and maintain accreditation. CLIA '88 requires external QC to be part of a QA program in order to receive accreditation. Laboratories are required by federal agencies to monitor how patient specimen results statistically compare to other laboratories or the "peer group." Proficiency testing uses unknown patient specimens to monitor procedures, instruments, and technicians. External laboratory monitoring can include regional, state, federal, and professional programs (e.g., CAP surveys). The data analyses from these programs can provide

invaluable information on your total QA program. For specific information on your laboratory's QA and QC programs, consult your OIs, OIC, or technical supervisor.

Laboratory safety

Laboratory safety is also an element that a QA program monitors. Safety programs are not only for the benefit of laboratory personnel but also for patients and other hospital personnel. We thoroughly cover laboratory safety later.

006. Purpose and content of operating instructions

OIs are step-by-step instructions or guidelines for everything you do in the laboratory. They are designed so that you can read the instructions and then perform the procedure, even if you haven't seen the procedure or instrument before. This lesson discusses their purpose and content. Although we provide only a general format, after reading this lesson, you should be able to write your own OI.

Purpose of OIs

One of the purposes of an OI is to ensure that regardless of who is doing the procedure, it is being done exactly the same way every time. The OI provides standardization that helps ensure accurate and precise specimen results that enhance overall patient treatment. OIs are also important when training new personnel: trainees learn the correct way the first time and become familiar with the procedure's reference. If you are new to a laboratory and being trained on a new procedure or instrument, the first thing you ask for is the OI.

Contents of an OI

OIs are only as good as their content and how easily understood they are. Remember, they need to be written at a level everyone can understand. NCCLS publishes GP2-A4, *Clinical Laboratory Technical Procedure Manuals; Approved Guideline*, which must be used by all Air Force laboratories. The following information is a paraphrase from this guideline. Let's start at the beginning or top of an OI.

OI heading, number, and title

The heading and number of your OI is designated by your unit or medical treatment facility (MTF) functional area records manager (FARM). The following examples of the heading, numbers, and title are only for illustrative purposes in this CDC.

The 82 Medical Group, Sheppard AFB is an example of an OI heading. Laboratory OIs are in the 44, or Medical, series; therefore, the OI number begins with 44. A letter designation can be used to identify a section within the laboratory (e.g., *C* for chemistry, *H* for hematology, *M* for microbiology, *A* for Administration, etc.). The OI number may look like this: OI 44C – 001; OI 44H – 031, OI 44M – 053; or OI 44A – 108. The title is descriptive and the word order based on the usual laboratory inquiry (e.g., CK Isoenzymes in Serum by Electrophoresis). Distribution must also be annotated as prescribed by the FARM.

Principle/purpose/introduction

This section of the OI is mandatory and describes the principle, purpose, or provides a general introduction. Write the *principle* in paragraph form and include a brief statement of (1) the type of reaction, specimen, or organism and (2) the clinical reasons for performing the test (if appropriate). When writing an OI for administration, you can use the *purpose* or *introduction*.

Specimen

This portion of the OI identifies patient preparation, if any; type of specimen (plasma, serum, etc.); anticoagulant or preservative; required specimen amount; acceptable collection containers; storage and stability; criteria for specimen rejection, special handling, or processing procedures; and physical characteristics (e.g., hemolysis, lipemia, icteric, etc.) that may compromise the results.

Reagent(s)

Included in this section are the name, source, preparation, storage, stability, labeling (substance, concentration, lot number, date prepared or opened, expiration date, preparer's initials), hazard statement, description of procedure, or validation/verification of the acceptability of the reagent(s). In this area, a list of special supplies can be provided.

Calibration

The calibration section lists standards or calibrators used, their preparation, storage, and stability. Also, there is a description of the calibration procedure, frequency, acceptable limits, and corrective action if control results were unacceptable following calibration. If needed, the section includes a description of the preparation of the standard curve, an example of the curve, and how to use it to obtain results.

Quality control

Contained in this section are the identity of control materials; preparation and handling; storage and stability; frequency of assay; tolerance limits (including how limits are established); corrective action; and documentation of control data.

Procedure

The procedure section must give concise, step-by-step instructions on how to perform the procedure. Write this section in an active voice, not passive. An example of this would be, "Fill the container with reagent grade water," rather than "The container is filled...." You must remember to write the steps so they are easily understood and without room for interpretation.

Calculations

This section includes equations in basic form, steps involved in simplification of the equation, and an example. This is critical for manual calculations, but if the instrument gives the calculated results, a general explanation is acceptable.

Reporting results

Here you clearly state the *reference range* (if appropriate) and how you established it. Also include an explanation on how to report results and values that require special notification (e.g., panic/alert values); expected values; and interpretation, if needed.

Procedure notes

This section must contain special precautions, sources of error, helpful hints, and any information that might be important that isn't contained in another section.

Limitations of the procedure

Include statements on linearity, detection limits, pitfalls, and known interfering substances. Basically, anything that would affect the test value is in this section.

References

The reference section contains just that, references or texts used in establishing procedures. If it is a textbook reference, you need the author, title, edition, publisher and address, year published, chapter, and page(s) number(s). If it is a manufacturer reference, the manufacturer's name or location, title of literature, publication code number, and revision date are required. You can also use standards, journals, and guidelines; they require the same above information if available.

Prepared by

This block is the author's signature block. This block will contain the name of the person who prepared the OI, his or her signature, and the date signed. Also, you need an approval signature block.

Approved and reviewed

Usually the medical director, the OIC, the superintendent, the NCOIC, or the section supervisor approves the OI. The approval signature and date must precede the implementation date. The implementation date corresponds to the adopted date on the last page of the OI. Review all OIs at least annually and whenever the procedure is modified. During the annual review, the procedure may be reapproved as currently written or it may be revised or determined to be obsolete and rescinded. Document annual reviews on the appropriate lines indicating the review, on the last page of the OI.

OI changes

Changes can be suggested by anyone using or reviewing the OI to the author or the individual responsible for the OI. The approving authority or a designee makes the changes. All changes must be dated and initialed. Minor changes you can accomplish by drawing a single line through the entry that is to be changed, then initialing and dating the entry. Major changes require the OI to be rewritten incorporating the new changes. Once changes are made, do an OI review or appropriate training document it.

Review

This unit has provided a lot of information, and you may feel you have information overload. For now, take a deep breath and relax. If at a later date, you have any questions, again, check the bibliography for additional reading material. You can also talk to your OIC, NCOIC, or technical supervisor about areas that are confusing or of concern to you.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

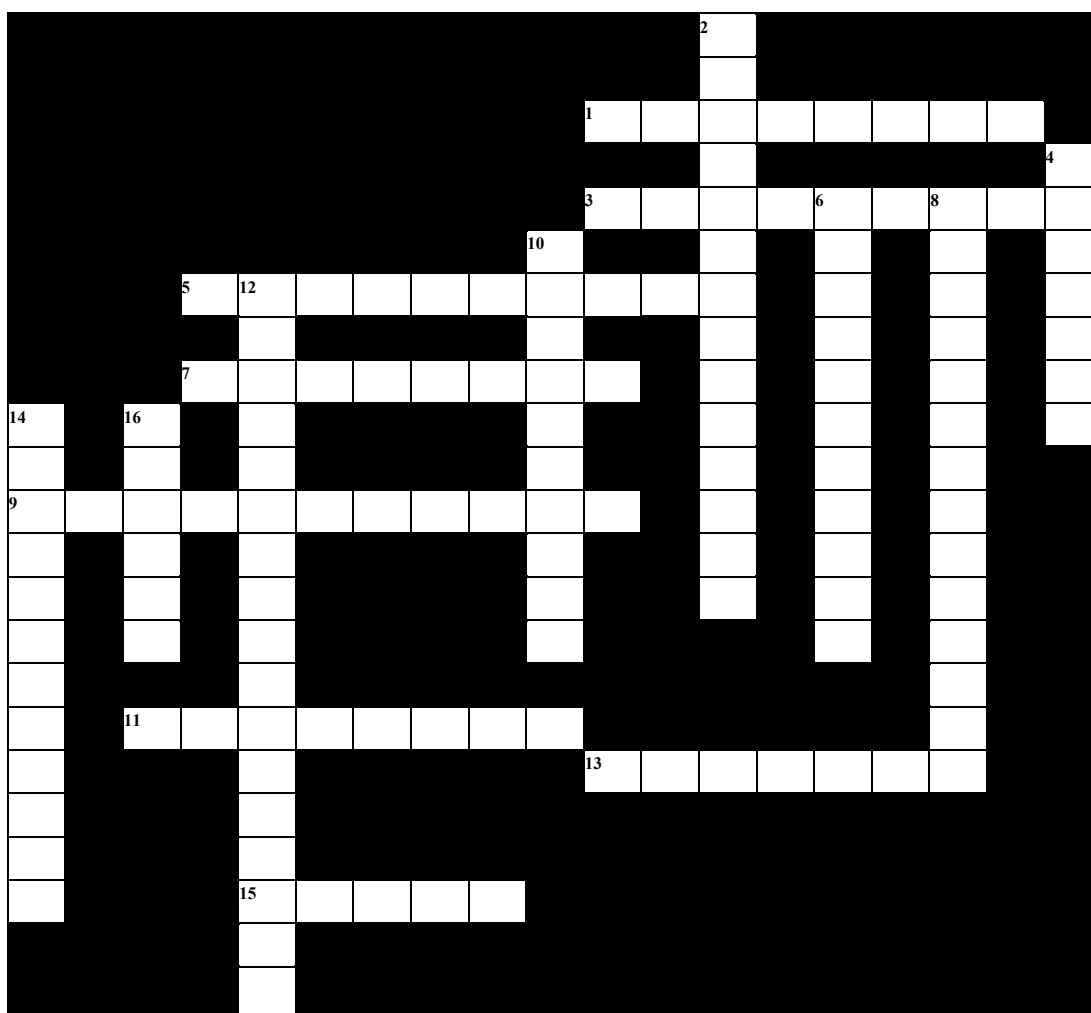
005. Quality assurance

1. Match the quality improvement terms in column B with the statements in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

<i>Column A</i>	<i>Column B</i>
____ (1) This area is so important within the laboratory arena that requirements for competence folders (OJT records) have been established.	a. Nonanalytic control.
____ (2) A material or device of known or assigned quantitative and/or assigned qualitative characteristics (e.g., concentration, activity, intensity, and reactivity).	b. Preanalytical.
____ (3) A standard, generally having the highest meteorological quality available at a given location or in a given organization, from which measurements made there are derived.	c. Postanalytical.
____ (4) Researched thoroughly before implementation; kept up-to-date and evaluated periodically.	d. Internal QC.
____ (5) Program done on a day-to-day basis to monitor normal analytical performance.	e. External QC.
____ (6) A device, solution, lyophilized preparation, or pool of collected human or animal specimen, or artificially derived material, intended for use in the quality control process.	f. Individual competence.
____ (7) Validating results, reporting results, workload recording or test charging, and storing specimens.	g. Equipment.
____ (8) A substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.	h. Procedure or method.
____ (9) Control materials that have a specific range with a known mean.	i. Reference ranges.
____ (10) Laboratory chemicals, including water.	j. Instrument.
____ (11) Usually pooled material; laboratory must establish its range for each control.	k. Reference materials.
____ (12) May be the single most important component of a good QC program.	l. Reference standard.
____ (13) Components of samples, other than the analyte, that alter the final result and in-turn affect the accuracy of the analytical method.	m. Calibration material.
____ (14) CLIA '88 requirement in order to receive accreditation.	n. Control material.
____ (15) An expression used to describe the permissible range into which a control must fall to be considered in control.	o. Reagents.
____ (16) Encompasses all activities not directly associated with the performance of the clinical assay itself.	p. Interfering substances.
____ (17) Checked for cleanliness, condition of electrical elements, stability of electrical current, and the temperature of refrigerated or heated analyzer compartments documented on a daily basis.	q. Assayed.
____ (18) Each laboratory should establish its own.	r. Unassayed.
____ (19) Exhibit and help identify problems with controls.	s. Standard deviation.
____ (20) Ordering test; ensuring correct patient identification and preparation; specimen collection, transport, identification, and accessing; and specimen processing for analysis.	t. Control charts.
____ (21) Designed to detect inappropriate bias or imprecision that may change the quality of the specimen result.	u. Westgard multirules.
	v. Documentation.

006 Purpose and content of operating instructions

- Complete the following crossword puzzle using words or terms associated with the content of operating procedures.



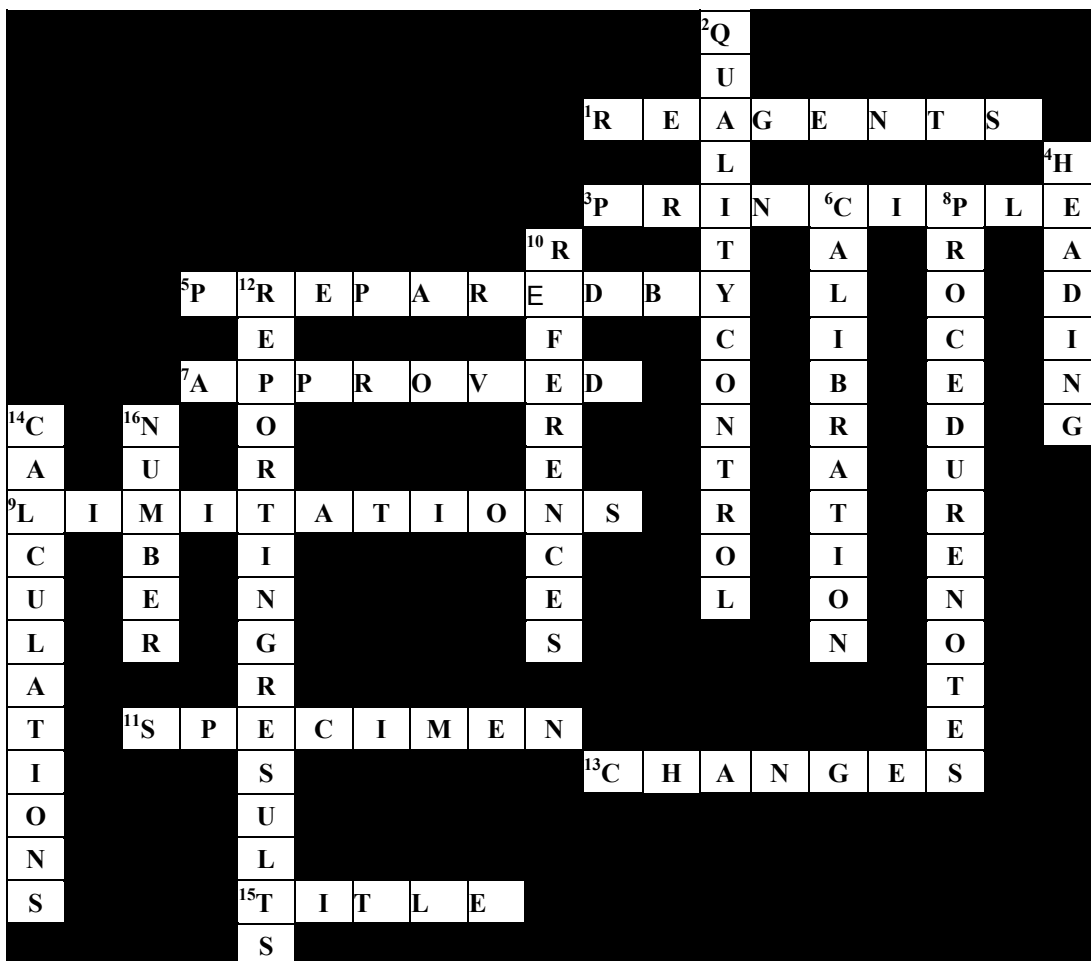
ACROSS	DOWN
1. In this area, a list of special supplies can be provided.	2. Identifies tolerance limits, frequency of assay, corrective action, and stability.
3. This section is mandatory, includes type of reaction, and clinical reasons for the test.	4. Designated by unit MTF FARM (place of origination).
5. Contains the author's signature block.	6. List standards, their preparation, storage, stability, and how to prepare standard curve.
7. The OIC's or NCOIC's signature can appear here.	8. This section should contain special precautions, sources of error, and hints.
9. Includes statements on linearity, pitfalls, and known interfering substances.	10. Contains the texts used in establishing procedures.
11. This area identifies patient preparation, criteria for rejection, and special handling.	12. Clearly states reference range, expected values, interpretation, and panic values.
13. Can be suggested by anyone using or reviewing the OI, must be dated and initialed.	14. Includes equations in basic form, steps involved, and an example.
15. This should be descriptive and word order based on the usual laboratory inquiry.	16. Designated by unit MTF FARM; in the Medical series.

Answers to Self-Test Questions

005

1. (1) f.
- (2) m.
- (3) l.
- (4) h.
- (5) d.
- (6) n.
- (7) c.
- (8) k.
- (9) q.
- (10) o.
- (11) r.
- (12) v.
- (13) p.
- (14) e.
- (15) s.
- (16) a.
- (17) j.
- (18) i.
- (19) t.
- (20) b.
- (21) u.

006



Do the unit review exercises before going to the next unit.

Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter.

9. (005) Which is *not* part of analytical quality control?
 - a. Equipment.
 - b. Reporting results.
 - c. Procedure or method.
 - d. Individual competence.
10. (005) Which is *not* a reason for performing method validation?
 - a. Major reagent changes.
 - b. Major part replacements.
 - c. Implementation of a procedure.
 - d. Lot number change on a test kit.

11. (005) Which may be due to deteriorating reagents or improper instrument calibration?
 - a. Shift error.
 - b. Random error.
 - c. Systematic error.
 - d. Indeterminate error.
12. (006) In an OI, where would you find panic or alert values?
 - a. Principle.
 - b. Procedure notes.
 - c. Reporting results.
 - d. Limitations of the procedure.
13. (006) Which does *not* apply to approval and review of OIs?
 - a. Major changes require a review.
 - b. They must be reviewed annually.
 - c. Minor changes do not require a review.
 - d. The approval signature and date must precede the implementation date.

Please read the unit menu for unit 3 and continue. ➔

Unit 3. Laboratory Safety

3–1. Air Force Occupational and Environmental Safety, Fire Protection, and Health	3–1
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SAFETY, SAFETY, SAFETY—it seems to be all you hear lately. The Air Force loses thousands of dollars a year to safety-related incidents, but most significant is the loss of life. By actively promoting safety, the Air Force hopes to save lives and money. Safety is so important to the Air Force that a publications series is devoted to it. Series 91, Safety, contains Air Force Policy Directive (AFPD) 91–1, *Nuclear Weapons and Systems Surety*; AFPD 91–2, *Safety Programs*; and AFPD 91–3, *Occupational Safety and Health*. Also, Series 48, Aerospace Medicine, addresses the entomology, epidemiology, and food safety topics related to safety. There are over 50 Air Force publications on this topic. This unit is an overview of the most meaningful medical laboratory safety areas.

3–1. Air Force Occupational and Environmental Safety, Fire Protection, and Health

Safety, like a party guest, must be entertained, sustained, and maintained throughout your existence, not only as an active duty military member, but throughout your life. Safety is not just an Air Force issue but is found at all levels of government through policy documents, and so forth. As a result, many of our policies, directives, and instructions are developed from these documents. This section explains the significance of the Air Force Occupational and Environmental Safety, Fire Protection, and Health (AFOSH) Program (Air Force Instruction [AFI] 91–301) and standards (AFI 91–302).

007. Purpose of AFOSH Program

There are three general considerations for safety in the Air Force. First, you are a highly trained and valuable resource; therefore, the Air Force doesn't want you to be "wasted" by a needless accident. Second, you must practice safety procedures for your own protection as well as for your coworkers. And, third, you have the responsibility to (1) be aware of safety hazards, (2) follow policies and procedures designed to protect you, and (3) report all incidents or accidents so that the organization can take steps to prevent recurrence. Laboratory safety programs are required for the protection of all personnel, patients, and equipment. Because of health, monetary, legal, and environmental involvement, such programs deserve attention from all laboratory workers. Safety awareness enables you to recognize the hazards within the medical laboratory.

AFOSH Program

The purpose of the AFOSH Program is to protect all Air Force personnel from work-related deaths, injuries, and occupational illness. It includes all safety, fire prevention, and health activities that affect the safety and health of Air Force personnel at their workplace. The program is governed by AFI 91–301, *Air Force Occupational and Environmental Safety Fire Prevention, and Health (AFOSH) Program*. The program requires that commanders provide all Air Force personnel a safe and healthful work environment in which recognized hazards have been eliminated or controlled. It requires that Air Force facilities and work areas, such as hospital laboratories (and their equipment), comply with safety, fire, and health guidance. The program further requires that unsafe and unhealthy working

conditions be eliminated or controlled through the use of engineering changes, administrative controls, or revised procedures. Qualified safety, fire prevention, and health personnel are required to inspect all workplaces for compliance with occupational safety and health requirements. Personnel must have access to Occupational Safety and Health Administration (OSHA) standards and AFOSH Program standards, along with safety and health program procedures.

AFOSH Program standards

AFOSH Program standards set ground rules for the safety program and ensure the highest level of safety possible. The development of AFOSH Program standards is covered in AFI 91-302, *Air Force Occupational and Environmental Safety, Fire Protection, and Health (AFOSH) Standards*. The purpose of AFOSH Program standards is to assist the commanders and supervisors in maintaining a safe environment and to administer a safety program that conforms to Air Force directives. AFOSH Program standards are derived from the OSHA guidelines. However, not all Air Force-unique safety issues are covered by OSHA standards. Also, some safety areas aren't adequately addressed by OSHA; hence, AFOSH Program standards are developed.

AFOSH Program standards affecting laboratory functions

Due to the wide variety of materials in the medical laboratory, several AFOSH Program standards apply directly to us. Let's examine some of these standards.

AFOSH Standard 48-8

AFOSH Standard 48-8, *Controlling Exposures to Hazardous Materials*, establishes occupational exposure limits (OEL) for airborne chemical concentrations. Health hazards are caused by exposure to levels of hazardous materials that can produce toxic effects. These exposures can be long or short term. OELs are used to define hazardous chemical exposures to chemical substances in order to control or eliminate these hazards. The mere presence of a hazardous material does not necessarily create a hazard. An exposure must include a source, pathway, and receiver. If the pathway is interrupted or controlled or the receiver's exposure is less than the OEL, then a health hazard doesn't exist. It is the function of the OEL to prevent this exposure. For a detailed list of OEL materials, contact your Bioenvironmental Safety Department or OSHA Standard 29, CFR 1910 Subpart Z, *Toxic and Hazardous Substances*.

Occupational exposure

Occupational exposures occur through inhalation, ingestion, skin contact, and skin absorption. Training programs must portray hazardous materials in a straightforward manner so that they are treated with the proper respect but aren't feared. The belief that you can "sense" harmful exposures is incorrect. Levels that produce chronic effects are often at lower concentrations than levels that cause odor or irritation. These substances, known as having "poor warning properties," can only be detected through external means. On the other hand, some materials, such as acids and bases, have a very bad reputation and are often viewed with unwarranted fear. You can use all chemicals safely if you follow the proper precautions.

AFOSH Standard 48-22

OSHA Standard 29, CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*, and AFOSH Standard 48-22, *Occupational Exposure to Hazardous Chemicals in Laboratories*, define the minimum requirements for an effective chemical hygiene program for Air Force laboratories. This AFOSH Program standard states the requirements for a chemical hygiene plan (CHP), assigns responsibilities, and provides guidance for protecting workers from hazardous chemicals used in the laboratory work environment. AFOSH Standard 48-22 divides chemical hazards into two categories: health hazards and physical hazards.

Health hazards

Health hazards can be caused by routine exposure to chemicals that produce toxic effects from short-term (acute) exposures, long-term (chronic) exposures, or both. Chemical exposures occur through inhalation, ingestion, skin surface contact, and skin absorption. Health effects from these exposures vary from minor irritation and temporary illness to permanent organ damage and cancer. When the body absorbs certain substances in combination, those substances produce greater damage than when absorbed separately in a process called “synergy.” Synergistic effects pose a concern because laboratory workers often use many different substances to cause reactions.

Physical hazards

Chemical physical hazards include fires and explosions. Increased attention is required when mixing incompatible materials. Other hazards associated with laboratory chemicals include splashes, spills, and broken containers. Always read equipment technical manuals for safety instructions before performing maintenance procedures.

AFOSH Standard 161–21

AFOSH Standard 161–21, *Hazard Communication Training Program*, establishes the minimum requirements for an effective hazard communication program for activities that handle or use hazardous materials. It outlines requirements for procedures, assigns responsibilities, and provides guidance for managing the Air Force Hazard Communication Program (AFHCP). The purpose of AFHCP is to reduce the incidence of chemically induced occupational illnesses and injuries by informing employees of the hazards associated with, and proper preventive measures to be taken when using or handling, hazardous materials in the workplace. It applies to all US civilian and military employees and direct-hire foreign nationals of the Air Force, National Guard, and Air Force Reserve and indirect-hire foreign employees of the same.

Requirements of a Workplace Written Hazard Communication Program

Elements of a Workplace Written Hazard Communication Program (WWHCP) include a written program, hazardous chemical inventories, hazard determinations, Material Safety Data Sheets (MSDS), labeling of hazards, and employee information and training. These elements must be addressed for all Air Force routine operations and nonroutine tasks and contractor operations as they impact Air Force operations involving the handling or use of hazardous materials.

Nonroutine tasks involving hazardous materials

In the laboratory, you may occasionally perform duties that are not part of your normal daily routine. The WWHCP addresses these issues. It is the supervisor’s responsibility to see that they do. Descriptions of nonroutine tasks are duties included within a work area’s normal activities but performed infrequently (e.g., cleaning up chemical spills) and temporary duties outside an individual’s Air Force specialty code (AFSC). For infrequent tasks performed in his or her work area, it’s the supervisor’s job to ensure OIs thoroughly describe nonroutine tasks, associated hazards, and controls. OIs aren’t required if technical orders (TO) or other official documents adequately describe these tasks. Supervisors ensure workers review these procedures before performing nonroutine tasks. When personnel temporarily perform duties outside their normal jobs, the supervisor of the activity ensures these workers receive the following training prior to beginning the activity:

- The initial Federal Hazard and Communication Training Program (FHCTP) described in paragraph 5e of AFOSH Standard 161–21, for workers not previously trained.
- Supplemental training, as necessary, on work area–specific chemical hazards and associated controls.
- The supervisor of the activity forwards a letter to the worker’s formal supervisor describing the training conducted so that the individual’s AF Form 55, Employee Safety and Health Record, can be updated.

Hazardous chemical inventory

The supervisor and base or attending support Bioenvironmental Engineering Services (BES) jointly develop an inventory of all hazardous materials used within the work area. Work areas where employees only handle materials in sealed containers that are not opened under normal conditions or use are not required to develop or maintain this inventory. Chemical inventory lists include, as a minimum, the name of the hazardous material as it appears on the MSDS. It is not necessary to have detailed descriptions of each item. This list is then attached to the WWHCP in each work area. The inventory list needs to be maintained and updated as necessary. BES reviews inventories annually or as needed.

Material Safety Data Sheets

BES maintains an MSDS master file for the installation. For installations without a BES function, the commander selects a qualified representative to maintain the MSDS master file. The master file must include MSDS information for all hazardous materials used on the installation. The representative maintains information in the DOD Hazardous Material Information System (HMIS) on microfiche, compact disc, or hard copy.

Labeling

All materials listed on the hazardous chemical inventory must have appropriate labeling. Information required on the label includes the identity of the hazardous material; appropriate hazard warnings; and the name, address, and phone number of the manufacturer, importer, or other responsible party. The labels must be easy to read; replace them if they are unreadable. See figures 3-1 and 3-2 for some examples of hazards labels. If you have any questions about the requirements for hazardous materials, contact the BES representative.

Employee information and training

All personnel, including civilian employees, are required to receive AFHCP training. This initial training must occur before employees are exposed to hazardous materials. If new materials, processes, operations, or conditions have hazards on which employees have already been trained, retraining is not required. With respect to federal civilian employees, their applicable collective bargaining agreement may contain procedures addressing labor's involvement with safety and health training. Employee and supervisor information and training addresses the items listed below:

- How employees can obtain and use the appropriate MSDS.
- Any operations in the work area where hazardous materials are present.
- Location and availability of the hazardous chemical inventory and MSDS master file.
- Methods and observations that may be used to detect the presence or release of a hazardous material in the work area such as monitoring conducted by BES, visual appearance and odor of hazardous materials, etc.
- Physical and health hazards associated with potential exposure to work area hazardous materials. An example of a hazardous material guide is shown in figure 3-3.
- The measures employees can take to protect themselves from hazards.
- Explanation of the labeling system.

We use the FHCTP or equivalent approved program for this training. The FHCTP is a generic program that covers all hazard classes included in the *OSHA Hazard Communication Standard*, 29 CFR 1910.1200. It contains a videotape program, a trainer's guide, and a student workbook. Supervisors need to supplement this training to provide information on work area-specific hazards and document all FHCTP training on AF Form 55, Employee Safety and Health Record. The supervisor maintains this document in the work area. The supervisor documents this information in Section V, Record of OSHA Briefing and Job Safety Training, for the initial FHCTP training. The supervisor documents training as "Workplace Specific FHCTP" for each presentation of specific

workplace hazard information. When a military member or civilian employee departs the base, the individual hand-carries AF Form 55 or a hard copy of the computerized training record to the Environmental Health Services (EHS) during out-processing actions.

HAZARDOUS CHEMICAL WARNING LABEL					
1. CHEMICAL/COMMON NAME Hydrochloric Acid					
2. HAZARD CODE 3		3. NSN/LSN 6810001450477			
4. PART NUMBER A00384-3					
5. ITEM NAME 0.72N Hydrochloric Acid [4L]					
6. HAZARDS (X all that apply)					
		NONE	SLIGHT	MODERATE	SEVERE
a. HEALTH				X	
b. CONTACT			X		
c. FIRE		X			
d. REACTIVITY				X	
7. SPECIFIC HAZARDS AND PRECAUTIONS (including target organ effects) (See MSDS for further information.) Corrosive. Proper wear of all required PPE is a must.					
8. PROTECT (X all that apply)					
X		EYES	X	SKIN	X RESPIRATORY
9. CONTACT a. COMPANY NAME Brand-Nu Laboratories					
b. ADDRESS (Street, P.O. Box, City, State, ZIP Code, Country) 377 Research Pkwy Meriden CT 06450					
c. EMERGENCY TELEPHONE NUMBER (Include Area Code) 800-243-3768 (Outside CT M-F 8am - 5pm)					
10. PROCUREMENT YEAR FOR HAZARDOUS CHEMICAL 2003					

DD FORM 2522, OCT 2000

PREVIOUS EDITION
MAY BE USED.

Figure 3-1. Example of a safety label for large containers.

CIRCLE ALL THAT APPLY	HAZARD TYPE	
0 1 <u>2</u> 3 4	HEALTH	Chemical HYDROCHLORIC ACID
0 1 <u>2</u> 3 4	REACTIVITY	Manufacturer Name/Address/Phone Number Brand-Nu Laboratories / 377 Research Pkwy Meriden CT 06450
<u>0</u> 1 2 3 4	FIRE	Open Date 20031216
A B C D E F <u>G</u> H I J K X	PERSONAL EQUIPMENT	Expiration Date 20041215



































SI035293035

Figure 3-2. Example of a small safety label.

Hazardous Material Identification

Hazard Ratings			
Degree	Health	Flammability	Reactivity
4-Extreme	Highly toxic. May be fatal on short-term exposure. Special protection	Extremely flammable gas or liquid. Flash point below 73°F.	Explosive at room temperature.
3- Serious	Toxic. Avoid inhalation or skin contact.	Flammable. Flash point 73°F to 100°F.	May explode if shocked, heated under confinement or mixed with water.
2 – Moderate	Moderately Toxic. May be harmful if inhaled or absorbed.	Combustible. Requires moderate heating to ignite. Flash point 100°F to 200°F.	Unstable. May react with water.
1 – Slight	Slightly toxic. May cause slight irritation.	Slightly combustible. Requires strong heating to ignite.	May react if heated of mixed with water.
0 – Minimal	All chemicals have some degree of toxicity.	Will not burn under normal conditions.	Normally stable – does not react with water.

Protective Equipment

A	Safety Glasses			
B	Safety Glasses - Gloves			
C	Safety Glasses - Gloves - Apron			
D	Face Shield - Gloves – Apron			
E	Safety Glasses - Gloves - Dust Respirator			
F	Safety Glasses - Gloves - Apron - Dust Respirator			 
G	Safety Glasses - Gloves - Vapor Respirator			
H	Splash Goggles - Gloves - Apron - Vapor Respirator			 
I	Safety Glasses - Gloves - Dust/ Vapor Respirator			
J	Splash Goggles - Gloves - Apron - Dust/ Vapor Respirator			 
K	Air line Hood/Mask - Gloves - Full Suit - Boots			 
X	Contact Supervisor for special instructions			

SI035293034

Figure 3–3. Example of a hazardous material guide.

General requirements of a comprehensive laboratory AFOSH Program

The elements of a complete laboratory safety and health program include the appointment of a chemical hygiene officer, a written chemical hygiene plan, OIs, properly maintained laboratory hoods and protective equipment, employee information and training, hazard identification through use of labels and MSDSs, employee exposure determinations, and medical consultation. These elements are addressed for all Air Force operations that are defined as “laboratories.”

008. Hazards and accident reporting

Hazard identification is critical to any safety program. Since the basic premise of the AFOSH Program is to protect personnel and equipment, it is imperative that we properly identify hazards before they cause an accident or harm. Every laboratory must have a standard procedure for reporting accidents. Report even relatively minor incidents, without personal injury, to the immediate supervisor. Reporting these incidents allows prevention processes to be put into place.

General documentation of hazards

Detailed and accurate records of hazards allow the supervisor a historical view, which in turn can help plan future actions. A record can pinpoint accident trends, high-hazard areas, and the frequency and severity of incidents involving personnel and equipment. All accidents must be investigated, documented, and reported. Well-documented incidents make the analysis of health records for future disability claims easier to interpret and evaluate. Accident reporting protects you, so don’t neglect it. Don’t let your coworkers forget it either; all of you are in a career field where occupational hazards are numerous.

Hazard prevention

The best way to prevent accidents is by applying AFOSH Program standards and laboratory guidelines. To do this, all personnel must fully understand all the relevant AFOSH Program standards for their work areas. Well-executed training programs and hazard identification help to decrease possible accidents. An effective mishap prevention program depends on individuals integrating prevention at every functional level.

Identifying hazards

Functional managers, supervisors, and individuals identify hazards by evaluating the work environment and job tasks. Safety, medical staff, and fire-prevention personnel can give technical assistance as needed. It is essential that everyone in the workplace identifies equipment and situations that place him or her at risk. You must report hazards to your supervisor if they have not been previously identified or correctly eliminated. This ensures corrective action can be taken. Safety inspections ensure hazards are continually identified and monitored.

Safety inspections

All Air Force facilities and work areas must be inspected at least once a year, unless otherwise directed. High-interest areas are usually inspected monthly by spot inspection and annually as a part of facility and work area inspections. Also, self-inspection checklists are performed as an internal measurement. These are usually performed annually in conjunction with other inspections, but they can be performed more often.

What hazards to report

Report any hazard that could result in injury to individuals or damage to equipment. The severity of the hazard determines if official paperwork is required. Reportable hazards include unsafe procedures, practices, or conditions. Once a hazard is identified, it needs to be assigned a Risk Assessment Code (RAC). The RAC is an expression of the degree of risk associated with an occupational hazard or deficiency. It combines hazard severity and mishap probability into a single numeric identifier. The health hazard severity category (HHSC) reflects the magnitude and medical

effects of exposure to a physical, chemical, or biological agent. The mishap probability category (MPC) reflects the duration of exposure and the number of exposed personnel. These two items are calculated and applied to a formula that determines the RAC. For complete information on these calculations, see AFI 91-301, *Air Force Occupational and Environmental Safety, Fire Protection, and Health (AFOSH) Program*.

Reporting procedures

Report all situations or conditions that have potential for injury or damage as a hazard. If the hazard can be eliminated on the spot, no further action is required unless the same problem applies to similar operations or other units and organizations. If the hazard cannot be eliminated immediately, an AF Form 457, USAF Hazard Report (HR), is required. The hazard reporting process is simple and is shown in the table below.

Hazard Identified	On-spot Correction	AF Form 457	AF Form 1118
Hazard description	Yes	No	No
Hazard description of hazard	No	Yes	Yes

The HR can be submitted in person or by telephone and can be submitted anonymously. Once this form is submitted, the safety staff investigates the HR. The investigator interviews the member who submitted the form (if known), the responsible supervisor, and any other parties involved. The interviews determine if the report is valid and what actions are to be taken.

Valid hazard

If the HR is validated, the investigator assigns a RAC and HR control number and monitors corrective action until completed. The investigator then completes the actions required to eliminate or control the hazard within 10 working days. If the corrective action taken is not satisfactory to the individual, he or she may submit a reevaluation request according to AFI 91-30, *Hazard Abatement Plan (HAP)*. If this is done, an AF Form 3, Hazard Abatement Plan, is generated and all corrective actions are then monitored through the HAP process.

AF Form 1118

The AF Form 1118, Notice of Hazard (NH), is posted at the site of the hazard once it is validated by the safety investigator. This form is a written warning of a procedure, condition, or practice that constitutes an occupational hazard. It also contains the action being taken, the date the hazard was identified, and the person responsible for the corrective action. This helps to eliminate duplicate hazard reports.

Review

As you can see, this small six-letter word, S-A-F-E-T-Y, is not a small subject, and it isn't taken lightly. Now that you know the laws, policy directives, standards, and instructions that govern safety, the next lesson takes a look at specific hazards that you should be aware of as a laboratory technician.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

007. Purpose of AFOSH Program

1. What is the purpose of the AFOSH Program?
2. What does the AFOSH Program include?

3. What is the purpose of AFOSH Program standards?
4. What establishes OELs, and how are OELs used?
5. How do occupational exposures occur?
6. For what does AFOSH Standard 48-22 define minimum requirements?
7. Into what two categories does AFOSH Standard 48-22 divide chemical hazards?
8. What are the WWHCP elements?
9. Who develops a hazardous chemical inventory, and what does it include?
10. What are the elements of a complete laboratory safety and health program?

008. Hazards and accident reporting

1. What does the documentation of hazards accomplish?
2. What is the best way to prevent accidents?
3. Who can provide technical assistance for identifying hazards?
4. What hazards are reported?
5. If the hazard cannot be eliminated immediately, what do you do?

3-2. Safety Hazards and Precautions

There are many hazards associated with working in a laboratory. The most important element of laboratory safety is achieved primarily through the education and training of laboratory personnel about safety procedures and equipment. To illustrate, fire extinguishers are useless if the people who need them don't know where they are or how to use them. Safety also involves educating personnel on the proper handling of chemicals, equipment, and infectious specimens and warning others, either verbally or written, on hazards in the laboratory. This may include a written notice or "sign" to alert housekeeping or visitors of the hazards in the area. For ease of discussion, we divide the various hazards into five broad categories: fire, electrical, mechanical, chemical, and biohazards. NCCLS and CAP collaborated on a joint safety guideline: *Clinical Laboratory Safety; Approved Guideline* (NCCLS document GP17-A). We recommend that you add this document to your reading list.

009. Fire, electrical, and mechanical hazards

Fire hazards within the laboratory have been reduced by the replacement of the Bunsen burner with hot plates and incinerators and replacement of flame photometry by modern analyzers. Even with these safety advancements, you still need to be safety aware at all times.

Fire

There are four basic factors that affect a fire: (1) nature of the fuel, (2) physical state of the fuel (liquid, gas, solid), (3) chemical nature of the fuel, and (4) oxygen availability. Fires are placed into four major classes, A through D, based on the fuel. Basic fire safety equipment includes the telephone and fire alarm system; fire-retarding doors; Class A, B, and C fire extinguishers; fire hoses; and fire blankets. However, the most important element of a good fire safety system is knowledgeable and trained personnel. This is reinforced through periodic fire drills and training. As shown in the table below, fire extinguishers are labeled according to the type of fire they are designed to extinguish. The correct extinguisher must be used or the fire may become worse. Use fire extinguishers only as intended. Additionally, familiarize yourself with the operating instructions and location of all fire safety equipment so that you'll know how to use it correctly.



Class of Fire	Substance Involved	Fire Extinguisher Class	Extinguishing Agent
Class A	Ordinary combustibles, such as wood, paper, or plastic	Class A	Water, water-loaded steam, aqueous film-forming foam, or halogenated agents
Class B	Flammable liquids	Class B	Carbon dioxide, aqueous film-forming foam, dry chemicals, or halogenated agents
Class C	Any fire involving energized electrical circuits regardless of fuel	Class C	Carbon dioxide, dry chemicals, or halogenated agents
Class D	Combustible metals	Class D	Dry powder

Volatile hazards

Volatiles pose more than just a fire or explosive threat. Don't forget, they can also be inhaled or ingested; therefore, you must take care when you use them. Each volatile substance has its own reaction characteristics. The flash point, in conjunction with the boiling point, determines the type of volatile substance. The flash point is the temperature at which a liquid gives off enough vapor to burst into flames when exposed to an ignition source. The boiling point is the temperature at which the vapor pressure of a substance equals atmospheric pressure. Based upon these values, we classify volatiles into two basic categories: *flammable* and *combustible*.



Flammable liquids have a flash point below 37.8°C (100°F). Turpentine and toluene are two examples. Combustible liquids have a flash point of 37.8°C (100°F) or greater, but below 93.4°C (200°F). Kerosene is an example.

Storage of volatiles

If refrigeration is necessary, we label volatile solvents as to their hazardous qualities and keep them in explosion-proof refrigerators. Use a safety cabinet for those items that do not require refrigeration. Maintain the amount or level of the solvents in accordance with their daily use. Handle all flammable and toxic liquids in a space with good ventilation, preferably a fume hood. Do not store excessive amounts and store all volatile substances in an approved container and in accordance with (IAW) OSHA, National Fire Protection Agency (NFPA) Standard 704, *Standard System for the Identification of the Hazards of Materials for Emergency Response*.

Miscellaneous volatiles

Combustible and flammable liquids are not the only kind of volatiles you may come into contact with. Depending on the laboratory, you may come into contact with *pyrophobics* and *oxidizers*. Pyrophobics are volatiles that ignite spontaneously in air below 54°C (130°F). This group includes very finely divided metals, metal hydrides, and carbon metals. Extreme care is required when using these chemicals. Oxidizers supply the oxygen required to start or support combustion. Nitric acid and chromic acid are two examples of oxidizing agents. Oxidizing agents are categorized as corrosives when discussing chemical categories. Like pyrophobics, extreme care is required when handling oxidizers due to their high fire or explosion hazard, especially during contact with oxidizable organic substances. Remember: You must *always* follow safety guidelines “to the letter.”

Electrical

Electrical hazards are caused by improper use or maintenance of electrical equipment. Inappropriate use can cause electrical shock, burns, fire, and/or explosions. Never plug in an instrument with wet hands or when any part of your body is in contact with water. Water completes the circuit and electrocution is the end result. You know that water and electricity are a dangerous combination, but, nonetheless, certain laboratory instruments contain water or other liquids. Immediately wipe up all spills and don't operate instruments with wet hands. Inspect equipment for frayed wires and electrical connections. Ground all equipment by using a three-pronged plug. Also, never overload an electrical outlet. By following these simple rules, you can avoid serious damage to you and your equipment. If you discover an electrical hazard, report it to your safety representative and supervisor.

Mechanical

Mechanical or physical hazards include laboratory layout, equipment, compressed gases, glassware, and sharp instruments. These hazards probably account for the majority of accidents within the laboratory. Why is this? Mechanical or physical hazards are usually associated with harmless looking items, like a heavy box on the top shelf, an open file or cabinet drawer, a small puddle of water by the sink, or the things you use daily. Don't let the simplicity of these hazards fool you. Inappropriate storage, usage, and disposal of these items can cause serious injuries.

Equipment

The best way to avoid equipment injury and ensure safety is to “always read the directions.” In the past, the centrifuge was probably the most misused piece of equipment with regards to safety. Technicians would stop the rotor with their hands. Do not centrifuge potentially volatile, toxic, or infectious substances in open tubes or containers. Recent standards require the use of buckets with safety caps for these substances. If a tube breaks in the centrifuge, turn off the centrifuge immediately. Allow 15 minutes for aerosols or droplets to settle within the centrifuge. Using protective equipment (e.g., rubber gloves, mask, face shield, etc.), clean the centrifuge with an

appropriate solution. Use a diluted acid for strongly alkaline solutions, sodium bicarbonate for acid solutions, and 5% sodium hypochlorite for potentially infectious material.

Compressed gas

Always follow guidelines for storage and handling of compressed gasses. Cylinders must be color-coded to indicate their contents. All cylinders must be securely fastened to the wall or bench or placed in floor holders so that they cannot overturn. If the cylinder falls, it can cause the outlet valve to rupture, and the cylinder may act as a torpedo and inflict serious injury and damage. If the cylinder is not in use, make sure the safety cap is securely in place. An improperly attached safety cap can act like a projectile if the valve ruptures. Also, when transporting a gas cylinder, be sure to tightly secure the cylinder to the cart. If any malfunction of the cylinder occurs, report it immediately.

Glassware and sharp instruments

Handle glassware carefully to prevent breakage and injury. Dispose of glassware and sharp objects in puncture-proof containers in order to avoid injury or exposure to infectious agents. Carefully handle and store sharp instruments (including needles) to avoid punctures or cuts. These items we usually place in a hard-plastic sharps container; separate from glass and other contaminated waste products (e.g., gloves, gauze, paper, etc.). Strict compliance is required; follow the MTFs uncontaminated and contaminated medical waste disposal procedures.

010. Chemical hazards

Chemical hazards can be difficult to address because everything you use in the laboratory contains chemicals, but of course, not all chemicals are dangerous. Nonetheless, you must review this area of safety. Exposure routes, hazard categories, basic chemical safety, and first aid are the items we cover in this lesson.

Exposure routes or mode of transmission

Exposure routes are ways that chemicals enter your body. There are four main exposure routes. These are described in the following table.

Route	Description
Inhalation/ breathing	Inhaling takes a chemical in through the nose or mouth, down the windpipe, and into the lungs. Some chemicals become trapped in the lungs, while others leave during exhaling. However, many chemicals enter the bloodstream from the lungs.
Ingestion/ swallowing	Ingestion takes a chemical from the mouth, down the esophagus, into the stomach. Many chemicals enter the intestines, where they can be absorbed into the bloodstream and spread throughout the body. Damage can occur at any point along this route.
Skin/eye contact	Can cause anything from reddening or itching to severe rashes, burns, loss of eyesight, or even death.
Skin absorption	Hazards pass through the skin into the bloodstream. Once in the bloodstream, they can spread throughout the body and cause injury or disease away from the original site of contact. Chemicals can also be absorbed through the mucous membranes of the eye.

Chemical hazard categories

There are a wide variety of chemical hazards; corrosives and carcinogens are probably the most common. Some of these hazards are described in the following table.

Hazard or Term	Description or Definition
Corrosives	Corrosives burn on contact, causing visible damage or irreversible changes to body tissues. Handle toxic corrosives, such as mercury salts and/or caustic acids or alkalis,

Hazard or Term	Description or Definition
	with extreme caution. Corrosives can cause potential harm through all of the exposure routes.
Irritants	React with the body at the site of contact, causing the skin to redden or itch. Repeated contact can crack or break the skin, but the damage is reversible (also considered a corrosive).
Carcinogenic	Carcinogens are chemicals that can cause cancer. Among these are aromatic amines, azo derivatives, sulfonic acid derivatives, and some inorganic chemicals (most widely known are asbestos and arsenic). Carcinogens are usually organ specific, but they can affect a wide variety of areas in the body. Carcinogens can undergo changes that may enhance or reduce their level of harm. These changes are caused by metabolic functions that are naturally occurring within the body.
Mutagens	Mutagens cause genetic changes in sperm and egg cells. This can cause sterility, birth defects, and miscarriages (also considered carcinogenic).
Teratogens	These are reproductive hazards that damage the fetus during its development (also considered carcinogenic).
Toxic	This is a substance that can cause serious biological effects that follow inhalation, ingestion, skin contact, and absorption with exposure to relatively small amounts.
Ignitable	This term is used to describe both flammable and combustible liquids (discussed earlier).
Explosive	Explosive chemicals are reactive and unstable substances that can readily undergo violent chemical changes.
Sensitizers	Sensitizers cause an allergic-like response in many people who are repeatedly exposed to the chemical. The response can happen on the second exposure or any exposure thereafter. (Not specific to any single group of chemicals.)
Cryogenics	These are very cold materials that cause frostbite by freezing body tissues on contact (e.g., liquid nitrogen and liquid oxygen).
Radiation	Radiation is electromagnetic energy emitted in the form of rays or particles from isotopes of different elements with radioactive properties. Radiation sickness is an abnormal condition resulting from exposure to radioactive chemicals. Symptoms and prognosis depend on the dose, exposure time, and the part of the body affected by radiation. Low to moderate doses cause nausea, vomiting, headaches, and diarrhea, potentially followed by hair loss and bleeding. Severe exposures can cause sterility, fetal damage, development of cataracts and some forms of cancer, and possibly death within hours.

Basic chemical safety

Basic chemical safety equipment includes acid and alkali chemical spill stations; mercury cleanup kits; protective clothing; monitoring devices and absorbent material for containing and decontaminating radioactive spills; and drench showers and eye washes for removing and diluting toxic or caustic chemicals. When handling hazardous chemicals, wear goggles, facemask, apron, and gloves, and work in an area where breaks or spills can be controlled. If considerable stirring is needed, you can use a magnetic stirrer to avoid splashing. In preparing reagents, use extreme care. Always add acid to water, *never* water to acid. Allow acid to run down the side of the container, mix slowly by gentle rotation, and avoid overheating.

Chemical fume hoods

The chemical fume hood is an important piece of safety equipment. Fume hoods have several functions. They are designed to prevent hazards from entering the laboratory by transporting fumes or contaminated particles through the roof to the outside air where they are diluted and become safe. Fume hoods decrease the chance of fire and explosion by diluting flammable vapors. They come in various sizes and types based on the hazardous chemicals they control. They can be customized to fit the need of any laboratory. Most fume hoods generally come with service fixtures (distilled water, gas, vacuum, etc.), electrical outlets, lighting, and airflow alarms. These accessories can be located internally and externally.

Radiation safety

Although most clinical laboratories have radiation exposure levels well below state and federal limits, due to the serious health problems associated with radiation, it is important to visit this subject. If your laboratory still utilizes radioisotopes in different techniques, then it must follow the Nuclear Regulatory Commission (NRC) regulations. All sections, containers, work areas, storage areas, and waste receptacles must be labeled with the appropriate warning sign. A radiation safety officer (RSO) is assigned and is responsible for monitoring all aspects that deal with radioactive materials (e.g., shipping, receiving, handling, security, storage, film badges, work areas, etc.). Laboratory personnel have the responsibility of wearing personal protective equipment (PPE), using recommended safety equipment (fume hoods, lead-lined containers, etc.), complying with all radiation safety policies, and reporting unsafe practices and accidents to supervisors. Radioactive spills require the notification of the RSO, laboratory director, and supervisor and that the incident be thoroughly documented. The actual spill area can be scrubbed with soap and water or a commercial cleaning compound designed for radiation decontamination. After cleansing, the area must be surveyed with a portable rate meter and by taking wipe samples. Those involved in the spill or cleanup must immediately remove any contaminated clothing and wash or shower.

First-aid procedures for chemical exposure

Limit first-aid procedures in the laboratory to those procedures that prevent further injury and preserve life before the affected individual receives medical attention.

Eye injuries

When chemicals enter the eye, immediately and thoroughly rinse the eye with plain water for 15 minutes. Remember that contact lenses prevent thorough irrigation; have the victim remove them to prevent further injury by chemicals. Call a physician, preferably a specialist, at the first possible opportunity. Locate eyewash stations throughout the laboratory and document training regarding their use. This is yet another reason why contact lenses are not recommended for wear in the laboratory. Is your eyesight worth risking?

Chemical burns

Irritating chemicals can instantly produce injury to skin or mucous membranes. Accordingly, begin first aid immediately. Chemicals such as acids, alkalis, or corrosive chemicals cause burns similar to those caused by fire, steam, or hot liquids. Use copious quantities of running water until you remove all traces of the chemical. Make no attempt to neutralize the chemical until you thoroughly irrigate all areas of contact. For example, you can neutralize chemical burns caused by acetic acid with a mild alkaline solution of sodium bicarbonate; you can neutralize sodium hydroxide with a 5% ammonium chloride or zinc chloride solution. However, if they aren't immediately available, don't waste time looking for or preparing these solutions. Remember, seek medical attention *immediately* after you give preliminary first aid. Do not apply oil or ointment of any kind to burned areas within the first 24 hours after contact or subsequently without the approval of the attending physician.

011. Biological hazards

In recent years, biological hazards have received the most attention, mainly due to the publicity of acquired immune deficiency syndrome (AIDS). Biological hazards are unique and dangerous because they can't be seen or smelled. Make your evaluation and control of biological hazards associated with laboratory operations in accordance with 29 CFR 1910.1030, *Occupational Exposure to Bloodborne Pathogens*. Let's look at some of the different areas of concern in regard to biological hazards.

Classes of biological hazards

Biological hazards we divided into three classifications. These classes are *etiological agents*, *oncogenic viruses*, and *recombinant DNA* (deoxyribonucleic acid). You'll study each of these and learn what kind of threat they pose to laboratory technicians.

Etiological agents

Agents that can produce disease in plants and/or animals we refer to as etiological agents. This covers the full range of microorganisms. For our purposes, you study four basic divisions of etiological agents: *bacteria*, *fungi*, *parasites*, and some *viruses*.

Bacteria

Bacteria are unicellular organisms that usually multiply by cell division and have a cell wall that provides a constancy of form. They may be free-living, saprophytic, parasitic, or pathogenic. Not all bacteria are considered pathogenic, yet they have to be treated as such because of their opportunistic nature. Any bacteria given the correct environment can cause disease to a human host. Since laboratory technicians work with a wide range of bacteria, you must always consider this hazard.

Fungi

The second class of biological hazards are the fungi. Fungi are eukaryotic organisms that generally have rigid cell walls and lack chlorophyll. Not all fungi infect humans; some are animal parasites. Fungi are generally not as emphasized as bacteria and viruses. However, they are a very diverse group and the disease processes can range from simple allergenic responses to deep tissue infections. Fungal infections are not usually transmitted from person to person, so they are not considered to be infectious. Exposure is usually due to inhalation or direct contact with the organism. Fungal diseases are called mycoses or mycotic diseases.

Parasites

Parasites are of a higher order than the other microbes that you have studied up to this point. In this category are protozoa (acellular or unicellular, single functional cell unit) and parasitic worms (round worms, tapeworms, and flatworms). These agents are transmitted through ingestion, inhalation of aerosols, and skin inoculation. They are responsible for a variety of symptoms.

Viruses

Viruses are microscopic infectious agents that reproduce in a living host and are also considered an etiological agent known to cause disease from the common cold to cancer. The difference between the viruses is the effect they have on the human body. Viruses are hard to cultivate and require a tissue culture medium. Most clinical laboratories don't cultivate viruses, but come into contact with virus-infected specimens. The most widely known virus of our time is the *retrovirus* called *human immunodeficiency virus* (HIV). The most serious viruses are oncogenic.

Oncogenic viruses

Oncogenic viruses cause cancer and tumors in humans. The danger of oncogenic viruses is that they can infect a host without causing any obvious symptoms. Later, they propagate and tumors appear. There are two main groups of oncogenic viruses: *DNA tumor viruses* and *RNA (ribonucleic acid) tumor viruses*. DNA tumor viruses have DNA in their genetic material that has the potential to cause malignant tumors in humans. Under this group are three families of viruses: *papovaviruses*, *adenoviruses*, and *herpesviruses*. There is only one family of oncogenic viruses that contain RNA in their genetic material. We know these viruses as *Retroviridae*.

Recombinant DNA

This biological hazard is associated with research using recombinant DNA procedures that remove genes from one organism and transplant them into a completely different organism. The dangers in

this type of research include many unknown reactions and the indiscriminate or careless use of these techniques.

Biohazard safety program

The basic strategy of a biohazard safety program is to prevent exposure to infectious disease agents. An excellent reference for biosafety is *Biosafety in Microbiological and Biomedical Laboratories*, a booklet by the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) in cooperation with the US Department of Health and Human Services.

Program fundamentals

Fundamentals of a biohazard safety program include procedures controlling access to the laboratory, the use of PPE, and correct specimen handling instructions. A biohazard safety program involves periodic assessment of exposure by skin testing, chest roentgenogram or serum antibody titers, and, if warranted, a vaccination or prophylactic treatment program that are tracked by Public Health at your MTF. Other fundamentals of a biohazard safety program include the proper disposal of infectious waste into covered and well-marked receptacles; the availability of sinks and a good-quality antiseptic soap; and readily available disinfectants. The air-handling system in a clinical laboratory is also a critical factor, ensuring that the airflow proceeds from areas of low risk to areas of high risk and replenishing it with outside air to reduce the biohazard burden on the auxiliary air-handling systems. The infection control manager, along with the civil engineers, is responsible for the air-handling system within the hospital.

Reducing biological hazards

We can avoid exposure by ingestion by frequent hand washing and the absolute elimination of mouth pipetting. The ban on smoking, applying cosmetics, and eating or storing food in the laboratory is vital. We can avoid direct inoculation by the careful handling and disposal of needles and broken glassware. Covering small cuts and abrasions helps prevent the spread of infectious agents.

Biological safety cabinets

Reducing or eliminating procedures that generate aerosols primarily prevents exposure to infectious agents by inhalation. Over the past 20 years, published data indicate aerosols of infectious agents are the largest source of potential laboratory acquired infections. Using biological safety cabinets or hoods to protect laboratory personnel from aerosol exposure of infectious agents is on the rise. In these cabinets, the infectious agents are usually sterilized by passing through a high-efficiency particulate air (HEPA) filter, although heat and ultraviolet light can also be used. There are three classes of biosafety cabinets. Classes I and II are “partial containment,” and Class III is “total containment,” which means it is totally enclosed with negative pressure.

Biosafety levels

In conjunction with good laboratory safety procedures, PPE, and biosafety cabinets, the assignment of biosafety levels to infectious agents helps inform and protect laboratory personnel. In the hospital laboratory, you do not routinely assign or think about biosafety levels, yet you may deal with known or identified infectious agents; for example, blood cultures drawn from an AIDS patient. Recommendations for biosafety levels for specific agents are made on the basis of the potential hazard of the agent and of the laboratory function or activity.

Pregnancy restrictions for USAF military personnel

Based on the hazards present, duty restrictions for pregnant laboratory personnel may be appropriate for some laboratories. These restrictions, if there are to be any, are determined by the patient’s obstetrical health-care provider, who works with Public Health personnel, Bioenvironmental Engineers (BEE), Flight Medicine, and the patient’s supervisor. Duty restrictions for active duty pregnant personnel are based on the patient’s work environment and overall medical condition, which

determine any profile action following AFI 44-102, *Community Health Management*, among others. These restrictions are to provide for fetal protection.

More information

The 4T051O course, *Microbiology*, provides more detail in the area of etiological agents and biological safety practices. Also, 4T051P, *Immunology*, discusses HIV, hepatitis viruses, and other biological hazards.

Infection control

Infection control and biohazard safety could be synonymous. However, infection control is a vital part of the MTF and, as such, we must discuss it. AFI 44-108, *Infection Control Program*, states that the MTF executive management team oversees the Infection Control Committee (ICC) or the clinical staff performing the Infection Control Review Function (ICRF) through the Executive Committee of the Medical Staff (ECOMS). The infection control program is an MTF-wide function that complies with current Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards, OSHA regulations, and other regulatory agencies. The ICC has the responsibility of ensuring compliance with the Department of Labor, Occupational Safety and Health Administration: *Occupational exposure to bloodborne pathogens*; final rule Federal Registry 56(235):64175-64182, 1991 as well as compliance with 29 CFR 1910.1030, *Occupational Exposure to Bloodborne Pathogens*, and 29 CFR 1910.20, *Access to Employee Exposure and Medical Records*. These are all important standards to follow for an effective Infection Control Program.

Infection Control Program

The program focuses on preventing and controlling infections in patients, staff, and visitors. It involves all MTF personnel, assigned Air Guard and Reserve personnel, personnel assigned in training and residency programs, and volunteers. Hospitals and freestanding clinics adapt the program's surveillance, prevention, and control activities to meet the needs of their specific facilities and services. The ICC annually reviews and approves the Exposure Control Plan and any OI that reflects exceptions or additions to this regulation, (e.g., specific PPE for certain performance activities within the work center). The elements of an Exposure Control Plan are exposure determination for all MTF personnel, standard precaution implementation, engineering and work practice controls, PPE, housekeeping, HIV and HBV (hepatitis B virus) research laboratories and production facilities, hepatitis A and B vaccinations, postexposure evaluation and follow-up, hazard communication, and recordkeeping.

Isolation precautions in hospitals

Isolation precautions in hospitals and "standard precautions" are the new buzzwords in the infection control arena. Appendix C, *Recommendations for Isolation Precautions in Hospitals*, from the Centers for Disease Control and Prevention, Public Health Service, US Department of Health and Human Services, states that transmission of infection within a hospital requires three elements. These are a source of infecting microorganisms (bacteria, viruses, mycobacterium, parasites, etc.), a susceptible host, and a means of transmission. The five main routes of transmission are contact, droplet, airborne, common vehicle (bed, linen, table, etc.), and vector-borne.

Isolation precaution fundamentals

There are a variety of infection control measures used for decreasing the risk of transmission of microorganisms in hospitals and clinics. The fundamentals of isolation precautions are hand washing and gloving; patient placement; transport of infected patients; masks, respiratory protection, eye protection, and face shields; gowns and protective apparel; patient-care equipment and articles; and linen and laundry. The Hospital Infection Control Practices Advisory Committee (HICPAC) isolation precautions consist of two tiers. The first tier, and the most important precautions, is designed for the care of all patients in hospitals, regardless of their diagnosis or presumed infection status—*standard*

precautions. The second tier is designed for specific patients with known or suspected microorganism infections—*transmission-based precautions*.

Standard precautions

Standard precautions synthesize the major features of the CDC's universal precautions and authors P. Lynch, et al., in the *American Journal of Infection Control's Body Substance Isolation*. Universal precautions were designed to reduce the risk of transmission of bloodborne pathogens. Body substance isolation was designed to reduce the risk of transmission of pathogens from moist body substances. Standard precautions apply information from both (universal precautions and body substance isolation) to *all* patients receiving care in hospitals, regardless of their diagnosis or presumed infection status. Standard precautions apply to blood; all body fluids, secretions, and excretions (except sweat), regardless of whether or not they contain visible blood; nonintact skin; and mucus membranes. Standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals.

Transmission-based precautions

Transmission-based precautions are designed for patients documented or suspected of being infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond standard precautions are needed to interrupt transmission in hospitals. The three types of transmission-based precautions are airborne, droplet, and contact precautions. These precautions may be combined for diseases that have multiple routes of transmission. When used either singularly or in combination, they are to be used in addition to standard precautions.

Review

You have just learned that safety is a very regulated area within the MTF and, in turn, the laboratory. Now that you have this background information, let's take a look at the actions you'll perform, or as some say, "where the rubber meets the road."

012. Laboratory safety requirements

A general safety program must include orientation of new laboratory personnel to the department's attitudes and policies for ensuring safe laboratory conduct. The following personal practices are standards followed in all laboratories, and it is important that you become familiar with them. Each technician is responsible for following all safety guidelines as they relate to procedures, reagents, and equipment in the laboratory. Thus, maintaining safe working standards may require extra effort, but risk reduction must be a part of getting the job done correctly.

Safety procedures

Let's review some basic laboratory safety procedures.

Hand washing

Hand washing has repeatedly been called the single most important action you can take to protect yourself and patients by preventing or reducing the transmission of disease. You must wash your hands frequently during work hours to remove any contaminating reagents or infectious agents. Wash your hands before donning and after doffing gloves; between patient contacts; before eating or smoking; and before leaving the laboratory.

Contact lenses

Don't wear contact lenses where eye hazards exist in the laboratory unless you wear them with approved goggles. Contact lenses, especially soft lenses, absorb solvents and constitute a hazard in splashes and spills because they offer no protection from a splash and may concentrate caustic material against the cornea or prevent tears from washing material away. Some authorities feel that contact lenses should not be allowed in the laboratory even when safety goggles are worn because of the inability to remove the lenses and wash the eye in an emergency. If it becomes necessary to

remove your contact lenses, don't replace them until they can be adequately cleaned and sterilized. While in the laboratory, never remove or apply your contacts.

Hand-to-face motions

Avoid hand-to-face motions when working with chemicals or infectious materials. For instance, don't rub your eyes or use any items (fingers, pens, etc.) to scratch your ears.

Cosmetic applications

Application of cosmetics in the technical work area is prohibited. Only apply cosmetics in designated areas after you wash your hands. This includes the application of lip balm or hand lotion.

Hair

Hair must be maintained in accordance with Air Force standards. It must be secured back and off the shoulders in such a manner as to prevent it from coming into contact with contaminated materials or surfaces as well as mechanical moving parts that might cause injury. Also, it prevents shedding of organisms into the work area.

Jewelry

Do not wear jewelry when handling infectious materials. If you wear jewelry in the laboratory, it must not interfere with the proper wear of PPE. Never wear dangling or loose-fitting jewelry because it may pick up and spread contamination and may get caught in equipment. It is best to remove jewelry prior to entering the laboratory.

Smoking

The Air Force prohibits personnel from smoking indoors. Smoke damages equipment and computers and may cause exposure to microorganisms.

Eating and drinking

Eating and drinking are prohibited in the technical work areas and are only allowed in designed break or administrative areas. All specimens have the possibility of transmitting a variety of pathogens; therefore, work areas could be contaminated with these pathogens. Eating or drinking in the work area provides hand-to-mouth contact that is hazardous. Also, the potential of contamination from the aerosol effects of reagents and infectious agents is a possibility.

Food and beverages

Food and beverages are not permitted in technical refrigerators. They must be stored in refrigerators that are designated for food only. The refrigerator must be used only for this purpose.

Standard precautions

In the laboratory environment, it is impossible to know if a specimen contains an infectious disease agent. For this reason, universal precautions were developed to protect you and others. Perhaps the most important occupational safety requirements that apply to blood-handling facilities are those contained in the bloodborne pathogens regulations issued and enforced by OSHA. They incorporate the CDC's universal precautions for the protection of health-care workers who have had exposure to HIV. You must handle and discard blood, its components, and other human tissues with precautions that recognize the potential for exposure to infectious agents. Remember, all devices that come in contact with blood are capable of transmitting infection. Common sense in this area can go a long way in ensuring your protection. Eventually, the lines between universal precautions and other exposure-limiting procedures begin to blur. This prompted the development of standard precautions, which is what the Air Force uses today. Standard precautions include many safety elements from other protection mechanisms. You will receive more extensive training locally from your unit.

Syringes and needles

You must pay attention to the proper disposal of syringes and needles to prevent accidental inoculation of laboratory personnel and custodial staff. The recommended method of disposal is by using “sharps” containers that can be autoclaved. These containers are designed to melt when autoclaved, fusing the needles and syringes together, rendering them unusable. You can then dispose of these materials properly. Use these containers only for needles and syringes. Some institutions also allow contaminated glass to be placed in these containers. Your laboratory OI establishes the acceptable method.

Mouth pipetting

Mouth pipetting of specimens and chemicals is prohibited; *never* do it. Pipetting aids are available for every task.

Laboratory equipment and work areas

Clean and disinfect refrigerators, freezers, water baths, and centrifuges periodically and when gross contamination occurs. Wear gloves, gowns, and other PPE as required during the cleaning. The OIs determine the frequency of cleaning. Disinfect work areas daily or more often if needed with a 10% sodium hypochlorite solution or other disinfectant approved by the ICC.

Housekeeping

Strictly adhere to uncontaminated and contaminated waste disposal procedures in your MTF or to the medical waste disposal contractor’s instructions.

Personal protective equipment

Policies on protective equipment vary with the type of laboratory and the type of work being performed. Such wear may range from the wear of a laboratory coat to a full body suit. PPE we also refer to as protective “barriers.” These barriers include gloves, face shields, protective eyewear, protective clothing, and ventilation devices. Protective barriers must not allow infectious materials to pass through to a person’s clothes or skin. Check all PPE routinely to ensure serviceability; discard and replace it if it is not serviceable. This ensures maximum protection.

Gloves

Always use the appropriate glove for the task you are performing. Gloves are manufactured in a variety of materials: cloth, leather, synthetic (neoprene) rubber (nitrile), natural rubber (latex), vinyl, or plastic. Wear the correct type of glove that provides protection from the hazard. In addition, it is important to be aware of the increasing numbers of people with latex allergies, whether they are patients or employees. It is contingent upon the facility to make alternatives to latex available for individuals with latex allergies. You can use any of the alternative items listed above in lieu of latex. Many facilities are taking steps to become latex-free.

Face shields or eye protectors

You must wear face shields or eye protectors when handling caustic or infectious materials when the potential for splashing is present. The type of shield depends upon the possible hazard. Always follow your section’s OI. You can also use a clear Plexiglas shield when manipulating blood samples. Using an absorbent material when removing stoppers from blood specimen tubes prevents aerosols.

Protective clothing

The purpose of protective clothing is to reduce the transfer of microorganisms from the lab to patients and vice versa, not to mention the protection of laboratory personnel. It is for this reason that you must never wear laboratory protective wear used in the section outside of the laboratory. Completely close (button, etc.) lab coats or gowns at all times. In addition to a lab coat, special solvent-resistant aprons may be required. This depends upon the substance with which you are working. Rubber aprons afford extra protection, especially when working with caustic or hot solutions.

Ventilation devices

Ventilation devices, such as masks, fume hoods, biosafety cabinets, or respirators, also vary depending upon the substance being handled. The general uses are designed to protect you from spills, fumes, and/or aerosols. In some instances, you must use respirators. The correct type of respiratory protection is designated in your OIs.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

009. Fire, electrical, and mechanical hazards

1. Fill in the missing fire safety information within the table below.

Class of Fire	Substance Involved	Fire Extinguisher Class	Extinguishing Agent
Class A			
Class B			
Class C			
Class D			

2. What kind of threats do volatiles pose?
3. What two factors do we use for determining the type of volatile substance?
4. What are the two basic categories of volatiles?
5. Where do you store volatiles?

6. What are pyrophobics? Give an example.
7. What are oxidizers? Give an example.
8. What can inappropriate use of electrical equipment cause?
9. List a few simple safety rules for operating electrical equipment.
10. What do mechanical and physical hazards include?
11. What is the best way to avoid equipment injury?
12. If an infectious specimen breaks within a centrifuge, how do you clean it up?
13. How do we store compressed-gas cylinders in the laboratory?

010. Chemical hazards

1. Match the chemical hazard terms in column B with the statements in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

*Column A**Column B*

- | | |
|---|----------------------|
| ___ (1) Chemicals that can cause cancer. | a. Inhalation. |
| ___ (2) Symptoms and prognosis depend on the dose, exposure time, and the part of the body affected. | b. Ingestion. |
| ___ (3) React with the body at the site of contact, causing the skin to redden or itch. | c. Skin/eye contact. |
| ___ (4) Are reproductive hazards that damage the fetus during its development. | d. Skin absorption. |
| ___ (5) A substance that can cause serious biological effects that follow inhalation, ingestion, skin contact and absorption with exposure to relatively small amounts. | e. Corrosives. |
| ___ (6) Cause genetic changes in sperm and egg cells; can cause sterility, birth defects, and miscarriages. | f. Irritants. |
| ___ (7) Once in the bloodstream, they can spread throughout the body and cause injury or disease away from the original site of contact. | g. Carcinogenic. |
| ___ (8) Burn on contact, causing visible damage or irreversible changes to body tissues. | h. Mutagens. |
| ___ (9) Can cause anything from reddening or itching to severe rashes, burns, loss of eyesight, or even death. | i. Teratogens. |
| ___ (10) This term is used to describe both flammable and combustible liquids. | j. Toxic. |
| ___ (11) Taking a chemical from the mouth, down the esophagus, into the stomach. | k. Ignitable. |
| ___ (12) Chemicals are reactive and unstable substances that can readily undergo violent chemical changes. | l. Explosive. |
| ___ (13) Taking a chemical in through the nose or mouth, down the windpipe, and into the lungs. | m. Sensitizers. |
| ___ (14) Are very cold materials that cause frostbite by freezing body tissues on contact. | n. Cryogenics. |
| ___ (15) Cause an allergic-like response in many people who are repeatedly exposed to the chemical. | o. Radiation. |

2. What is included in basic chemical safety equipment?
3. How do fume hoods prevent hazards?
4. What are the laboratory personnel responsibilities for radiation safety?
5. What is the first thing you do if a chemical enters your eye?
6. How do you treat corrosive chemicals that come in contact with the skin?

011. Biological hazards

1. What are the three classifications of biological hazards?
2. What are the four basic divisions of etiological agents?
3. What is the definition and danger of oncogenic viruses?
4. What are the two main groups of oncogenic viruses?
5. What are the dangers of recombinant DNA research?
6. List the fundamentals of a biohazard safety program.
7. What is the largest source of potential laboratory-acquired infections, and how can we reduce them?
8. What AFI and who oversees the Infection Control Program?
9. What is the focus of the Infection Control Program, and whom does it involve?
10. What are the elements of an Exposure Control Plan?
11. What are the three required elements of transmission of infection?
12. List the five main routes of transmission.
13. What are the fundamental isolation precautions?

14. What is the first tier in the HICPAC isolation precautions and its definition?
15. What is the second tier in the HICPAC isolation precautions and its definition?
16. What are the three types of transmission-based precautions?

012. Laboratory safety requirements

1. Match the laboratory safety requirement terms in column B with the statement in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

<i>Column A</i>	<i>Column B</i>
____ (1) Strict adherence to uncontaminated and contaminated waste disposal procedures in your MTF or the medical waste disposal contractor's instructions.	a. Hand washing.
____ (2) These barriers include gloves, gowns, face shields, masks, protective eye-wear, and ventilation devices.	b. Hand-to-face motions.
____ (3) Has repeatedly been called the single most important action you can do to prevent or reduce the transmission of microorganisms.	c. Application of cosmetics.
____ (4) If applied, needs to be done in a designated, uncontaminated area and only after adequate washing of your hands.	d. Contact lenses.
____ (5) Scratching your face, rubbing your eyes, or using foreign items (fingers, pens, etc.) to scratch or clean out your ears.	e. Hair.
____ (6) Must be secured back and off the shoulders in such a manner as to prevent it from coming into contact with contaminated materials or surfaces.	f. Jewelry.
____ (7) Do not wear where eye hazards exist in the laboratory unless you wear with approved goggles.	g. Smoking.
____ (8) One of the best ways to protect yourself and your patient.	h. Eating and drinking.
____ (9) Can cause exposure to microorganisms, toxic materials, and harm computers and other equipment.	i. Food and beverages.
____ (10) Proper disposal is required to prevent accidental inoculation of laboratory personnel and custodial staff.	j. Syringes and needles.
____ (11) Refrigerators, freezers, water baths, and centrifuges should be cleaned and disinfected periodically and when gross contamination occurs.	k. Mouth pipetting.
____ (12) Must be in a separate refrigerator away from any possible contamination.	l. Laboratory equipment.
____ (13) Is prohibited; do not perform.	m. Housekeeping.
____ (14) Prohibited in the technical work areas and only allowed in designated break areas.	n. PPE.

Answers to Self-Test Questions

007

1. To protect all Air Force personnel from work-related deaths, injuries, and occupational illness.
2. All safety, fire prevention, and health activities that affect the safety and health of Air Force personnel at their workplace.
3. To assist the commanders and supervisors in maintaining a safe environment and to administer a safety program that conforms to Air Force directives.
4. AFOSH Standard 48-8, *Controlling Exposures to Hazardous Materials*; OELs are used to define hazardous chemical exposures to chemical substances in order to control or eliminate these hazards.
5. In many ways: through inhalation, ingestion, skin contact, and skin absorption.
6. The minimum requirements for a chemical hygiene plan (CHP), assigns responsibilities, and provides guidance for protecting workers from hazardous chemicals used in the laboratory work environment.
7. Health hazards and physical hazards.
8. Program elements include a written program, hazardous chemical inventories, hazard determinations, MSDSs, labeling of hazards, and employee information and training.
9. The supervisor and base or attending support BES; chemical inventory lists include, as a minimum, the name of the hazardous material as it appears on the MSDS.
10. The appointment of a chemical hygiene officer, a written CHP, OIs, properly maintained laboratory-type hoods and protective equipment, employee information and training, hazard identification through use of labels and MSDSs, employee exposure determinations, and medical consultation.

008

1. A record can pinpoint accident trends, high-hazard areas, and the frequency and severity of incidents involving personnel and equipment.
2. Applying AFOSH standards and laboratory guidelines.
3. Safety, medical staff, and fire-prevention personnel can give technical assistance as needed.
4. Any hazard that could result in injury to an individual or damage to equipment.
5. Fill out an AF Form 457, USAF Hazard Report (HR), and AF Form 1118, Notice of Hazard.

009

1.

Class of Fire	Substance Involved	Fire Extinguisher Class	Extinguishing Agent
Class A	Ordinary combustibles, such as wood, paper, or plastic	Class A	Water, water-loaded steam, aqueous film-forming foam, or halogenated agents
Class B	Flammable liquids	Class B	Carbon dioxide, aqueous film-forming foam, dry chemicals, or halogenated agents
Class C	Any fire involving energized electrical circuits regardless of fuel	Class C	Carbon dioxide, dry chemicals, or halogenated agents
Class D	Combustible metals	Class D	Dry powder

2. Fire, explosive, inhalation, and ingestion.
3. Flash point and boiling point.
4. Flammable and combustible.
5. Explosion-proof refrigerators for refrigeration or a safety cabinet.
6. Pyrophobics are volatiles that ignite spontaneously in air below 130°F (54°C). Very finely divided metals, metal hydrides, and carbon metals.
7. Oxidizers supply the oxygen required to start or support combustion. Nitric acid and chromic acid.

8. Electrical shock, burns, fire, and/or explosions.
9. (1) Never plug in an instrument with wet hands or when any part of your body is in contact with water.
 (2) Immediately wipe up all spills and don't operate instruments with wet hands.
 (3) Inspect equipment for frayed wires and electrical connections.
 (4) All equipment must be grounded by using a three-pronged plug.
 (5) Never overload an electrical outlet.
10. Laboratory layout, equipment, compressed gases, glassware, and sharp instruments.
11. Always read the manufacturers' instructions.
12. Using protective equipment (e.g., rubber gloves, mask, face shield, etc.), clean the centrifuge with 5% sodium hypochlorite.
13. All cylinders must be securely fastened to the wall or bench or placed in floor holders so that they cannot overturn.

010

1. (1) g.
 (2) o.
 (3) f.
 (4) i.
 (5) j.
 (6) h.
 (7) d.
 (8) e.
 (9) c.
 (10) k.
 (11) b.
 (12) l.
 (13) a.
 (14) n.
 (15) m.
2. Acid and alkali chemical spill stations; mercury cleanup kits; protective clothing; monitoring devices and absorbent material for containing and decontaminating radioactive spills; and drench showers and eyewashes for removing and diluting toxic or caustic chemicals.
3. They are designed to prevent hazards from entering the laboratory, by transporting fumes or contaminated particles through the roof, to the outside air where they are diluted and become safe.
4. Responsibilities include wearing PPE, using recommended safety equipment (fume hoods, lead-lined containers, etc.), complying with all radiation safety policies, and reporting unsafe practices and accidents to supervisors.
5. Immediately, thoroughly rinse the eye with tap water for 15 minutes.
6. Use copious quantities of running water until you remove all traces of the chemical; then seek medical attention.

011

1. (1) Etiological agents.
 (2) Oncogenic viruses.
 (3) Recombinant DNA.
2. For our purposes, there are four basic divisions of etiological agents:
 - (1) Bacteria.
 - (2) Fungi.

- (3) Parasites.
- (4) Some viruses.
- 3. Oncogenic viruses cause cancer and tumors in humans; the danger of oncogenic viruses is that they can infect a host without causing any obvious symptoms.
- 4. DNA tumor viruses and RNA tumor viruses.
- 5. The danger in this type of research is there are many unknown reactions and the indiscriminate or careless use of these techniques.
- 6. They include procedures for controlling access to the laboratory, the use of PPE, and instructions for correct specimen handling.
- 7. Aerosols of infectious agents; reducing or eliminating procedures that generate aerosols.
- 8. AFI 44-108, *Infection Control Program*, states the MTF executive management team oversees the Infection Control Committee (ICC) or the clinical staff performing the Infection Control Review Function (ICRF) through the Executive Committee of the Medical Staff.
- 9. The program focuses on preventing and controlling infections in patients, staff, and visitors; all MTF personnel, assigned Air Guard and Reserve personnel, personnel assigned in training and residency programs, and volunteers.
- 10. Exposure determination for all MTF personnel, standard precaution implementation, engineering and work practice controls, PPE, housekeeping, HIV and HBV research laboratories and production facilities, hepatitis A and B vaccinations, postexposure evaluation and follow-up, hazard communication, and recordkeeping.
- 11. (1) Source of infecting microorganisms (bacteria, viruses, mycobacterium, parasites, etc.).
(2) A susceptible host.
(3) A means of transmission.
- 12. (1) Contact.
(2) Droplet.
(3) Airborne.
(4) Common vehicle (bed, linen, table, etc.).
(5) Vector-borne.
- 13. Hand washing and gloving; patient placement; transport of infected patients; masks, respiratory protection, eye protection, and face shields; gowns and protective apparel; patient-care equipment and articles; and linen and laundry.
- 14. Standard precautions; applies to all patients receiving care in hospitals, regardless of their diagnosis or presumed infection status; and applies to blood; all body fluids, secretions, and excretions (except sweat), regardless of whether or not they contain visible blood; nonintact skin; and mucus membranes.
- 15. Transmission-based precautions are designed for patients documented or suspected to be infected with highly transmissible or epidemiological important pathogens for which additional precautions beyond standard precautions are needed to interrupt transmission in hospitals.
- 16. (1) Airborne.
(2) Droplet.
(3) Contact.

012

- 1. (1) m.
(2) n.
(3) a.
(4) c.
(5) b.
(6) e.
(7) d.

- (8) a.
- (9) g.
- (10) j.
- (11) l.
- (12) i.
- (13) k.
- (14) h.

Do the unit review exercises before going to the next unit.

Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter.

- 14. (007) The AFOSH Program requires that commanders provide all Air Force personnel a safe and healthy
 - a. home environment in which recognized hazards have been eliminated or controlled.
 - b. work environment in which recognized hazards have been eliminated or controlled.
 - c. home environment in which recognized hazards have been identified.
 - d. work environment in which recognized hazards have been identified.
- 15. (007) The mere presence of a hazardous material does *not* necessarily create a hazard; an exposure *must* include a
 - a. source, pathway, and receiver.
 - b. source, pathway, and reservoir.
 - c. long-time exposure, pathway, and receiver.
 - d. long-time exposure, pathway, and reservoir.
- 16. (007) AFOSH Standard 48-22, *Occupational Exposure to Hazardous Chemicals in Laboratories*, divides chemical hazards into two categories—
 - a. health and physical.
 - b. health and electrical.
 - c. infectious and physical.
 - d. infectious and electrical.
- 17. (007) Which of the following includes a written program, hazardous chemical inventories, hazard determinations, MSDS, labeling of hazards, and employee information and training?
 - a. Air Force Occupational and Environmental Safety, Fire Prevention, and Health Program.
 - b. Workplace Written Hazard Communication Program.
 - c. Occupational Safety and Health Administration Program.
 - d. Air Force Hazard Communication Program.
- 18. (008) If a hazard *cannot* be eliminated immediately, an
 - a. AF Form 3, Hazard Abatement Plan (HAP), is required.
 - b. AF Form 3, Hazard Abatement Plan (HAP), is suggested.
 - c. AF Form 457, USAF Hazard Report (HR), is required.
 - d. AF Form 457, USAF Hazard Report (HR), is suggested.

19. (009) If an infectious specimen tube breaks in the centrifuge, turn off the centrifuge immediately, and
- allow 5 minutes for aerosols or droplets to settle and clean with 1% sodium hypochlorite.
 - allow 5 minutes for aerosols or droplets to settle and clean with 5% sodium hypochlorite.
 - allow 15 minutes for aerosols or droplets to settle and clean with 1% sodium hypochlorite.
 - allow 15 minutes for aerosols or droplets to settle and clean with 5% sodium hypochlorite.
20. (010) Which of the following causes genetic changes in sperm and egg cells?
- Mutagens.
 - Teratogens.
 - Cryogenics.
 - Corrosives.
21. (011) Which of the following is *not* a classification of a biological hazard?
- Carcinogens.
 - Etiological agents.
 - Oncogenic viruses.
 - Recombinant DNA.
22. (011) Oncogenic viruses cause
- cancer.
 - measles.
 - chickenpox.
 - mononucleosis.
23. (011) The largest sources of potential laboratory-acquired infections are
- needle sticks.
 - aerosols.
 - splashes.
 - spills.
24. (012) Store food and beverages in
- any freezer.
 - reagent refrigerators.
 - technical refrigerators if they are clean and uncontaminated.
 - a separate refrigerator away from any possible contamination.

Please read the unit menu for unit 4 and continue. ➔

Unit 4. Specimen Collection and Medical Terminology

4–1. Venipuncture and Skin Puncture Blood Collection	4–1
013. Patient instructions and equipment preparation.....	4–1
014. Blood collection by venipuncture.....	4–6
015. Blood collection by skin puncture.....	4–13
4–2. Specimen Processing and Medical Terminology	4–20
016. Specimen processing	4–20
017. Medical terminology.....	4–23
4–3. Point-of-Care Testing.....	4–30
018. Point-of-care testing	4–30

WHEN A TECHNICIAN—any technician—draws blood, he or she is representing the entire laboratory. The skill, patience, compassion, and understanding exhibited toward the patient during those few minutes will decide whether the laboratory is judged competent or incompetent. The reputation of the whole laboratory is based upon the few minutes you are in contact with each patient. If your venipuncture technique is exceptional, then the patient likely feels the rest of the laboratory is just as commendable. This unit focuses on reinforcing and improving blood-collecting techniques. We discuss the collection of other various body fluids, exudates, or tissue samples in that area of study (e.g., urine collection in urinalysis, throat culture in microbiology, etc.). You begin by reviewing specimen requests, patient instructions, and venipuncture equipment. Next, we examine venipuncture techniques, specimen processing, and medical terminology. Keep in mind, also, that just as your interaction with the patient is judged, your interaction with medical treatment facility (MTF) personnel is judged as well and will cause them to make assumptions about the competence and professionalism of your laboratory as well.

4–1. Venipuncture and Skin Puncture Blood Collection

“My daughter needs to have her blood drawn. Is MSgt Puterbaugh here?” You respond by stating that SrA Blount can draw her blood, but the patient’s family is insistent on having MSgt Puterbaugh. Naturally, we want the best for our children or ourselves. Technique is critical when drawing blood. The old adage “practice makes perfect” definitely applies to venipunctures. If you can make venipuncture a fine art and not drudgery, you too can be asked for by name!

013. Patient instructions and equipment preparation

Proper specimen collection requires knowledge of the routine and special methods employed in all disciplines in the laboratory. For the most part, laboratory personnel collect blood specimens. However, blood and other body fluids can be collected by physicians; emergency, ward, or clinic personnel; or patients. Thus, you must give specimen collection instructions to these individuals. Whether verbal or written, instructions must be accurate, concise, and clear. You also need to know the routine or special equipment required to collect specimens for all sections or areas within the laboratory.

Services request

The very first step in specimen collection is the order or request for the laboratory to perform a procedure or blood test. This can only be initiated by the patient’s health-care provider. The “lab slip” or requisition form can be a computer printout or any style of a manually filled-out form. Familiarize yourself with the various types of forms in your MTF. Nonetheless, whatever type of form or system your facility uses, each request must encompass the same type of information. This information includes patient’s name, Social Security Number (SSN) or hospital identification (ID) number, and

date of birth; physician's name; test ordered; date received; billing code; and room and bed number for inpatients.

Compassion for patients

As stated in the unit introduction, the patient judges the whole laboratory on just the few minutes you spend with him or her. Needless to say, the patient isn't thrilled about his or her laboratory visit, so a little compassion goes a long way. Being organized decreases the amount of time the patient has to remain in the "torture chair" or be disturbed in his or her hospital room.

Patient instructions

Instructions must be direct, fully explained, and professionally delivered. Some tests require the patient to fast or to eliminate certain foods from the diet before phlebotomy. Fasting entails that the patient has nothing by mouth except water and prescribed medications, meaning no tobacco products, mints, gum, and so forth. Such restrictions are needed to ensure accurate test results. However, except for glucose, triglycerides, and inorganic phosphorus, most chemical substances reveal no significant changes after a standard meal. Certainly, we must consider the effects of a cloudy specimen drawn after a meal. Typically, patients fast for 12 to 14 hours before blood collection because most baseline normal values are established using fasting samples. Prolonged fasting, for more than 24 hours, can lead to unexpected, as well as erroneous, laboratory results. For inpatients, ask when they ate last or get this information from the nurse. The laboratory guide provides specific patient preparation information.

Venipuncture equipment

Before doing a venipuncture or skin puncture, you must ensure that your supplies and equipment are clean, organized, and readily accessible, whether at a drawing station, on a cart, or in a tray. Supplies include gloves, antiseptic (alcohol pads), sterile gauze, bandages, slides, and needle or sharps disposal container. The equipment required is a tourniquet, needle, syringe or evacuated tube system, and various evacuated tubes with or without anticoagulants. Tourniquets can be a flat stretchable latex, elastic material with a Velcro closure, a cloth belt-like Seraket tourniquet, or a blood pressure cuff.

Needles

Needles are sterile and disposable (single-use), and they come in various sizes or gauges. The gauge you choose depends on the size and condition of the patient's vein. The larger the number assigned to the needle, the smaller the lumen or bore size of the needle. The bore size or gauge is the diameter of the interior shaft of the needle. The largest (smaller-gauge number) needle that you can use is best. Smaller (higher-gauge number) needles are good for veins that might collapse, but the smaller bore increases the chance for hemolysis; this must be a consideration. The end of the needle is cut on a slant to allow the needle to enter the skin; we call this slant the bevel. The long, cylindrical part varies in length (usually 1 or 1½ inches) and is known as the shaft. The end that attaches to the blood-drawing equipment is the hub (fig. 4-1). Always inspect each needle for burrs or other imperfections before you use it on a patient.

Syringes

Syringes are sterile and come in various sizes; the 2 to 10 milliliter (ml) is most commonly used for venipuncture. We use syringe systems for patients with small, fragile, poor, or difficult veins. You can control the vacuum pressure by gently pulling back on the plunger (fig. 4-1), thus avoiding collapsed veins. The needle gauges used with syringes are usually 23 or 21 gauge for drawing blood and 18 gauge for transferring specimen into evacuated tubes. As a lab tech of 18+ years, I invariably use a syringe for difficult draws. The advantage to me is that once the needle penetrates the vein, blood is visible in the hub (due to blood pressure). Hence, I know I am in the vein and can slowly pull back on the plunger. With an evacuated tube system, this is not possible. When I was responsible for

teaching clinical students, I had them begin with a syringe so they could “feel” and see the entry into the vein. Once they exhibited proficiency in this area, I let them use the evacuated tube system.

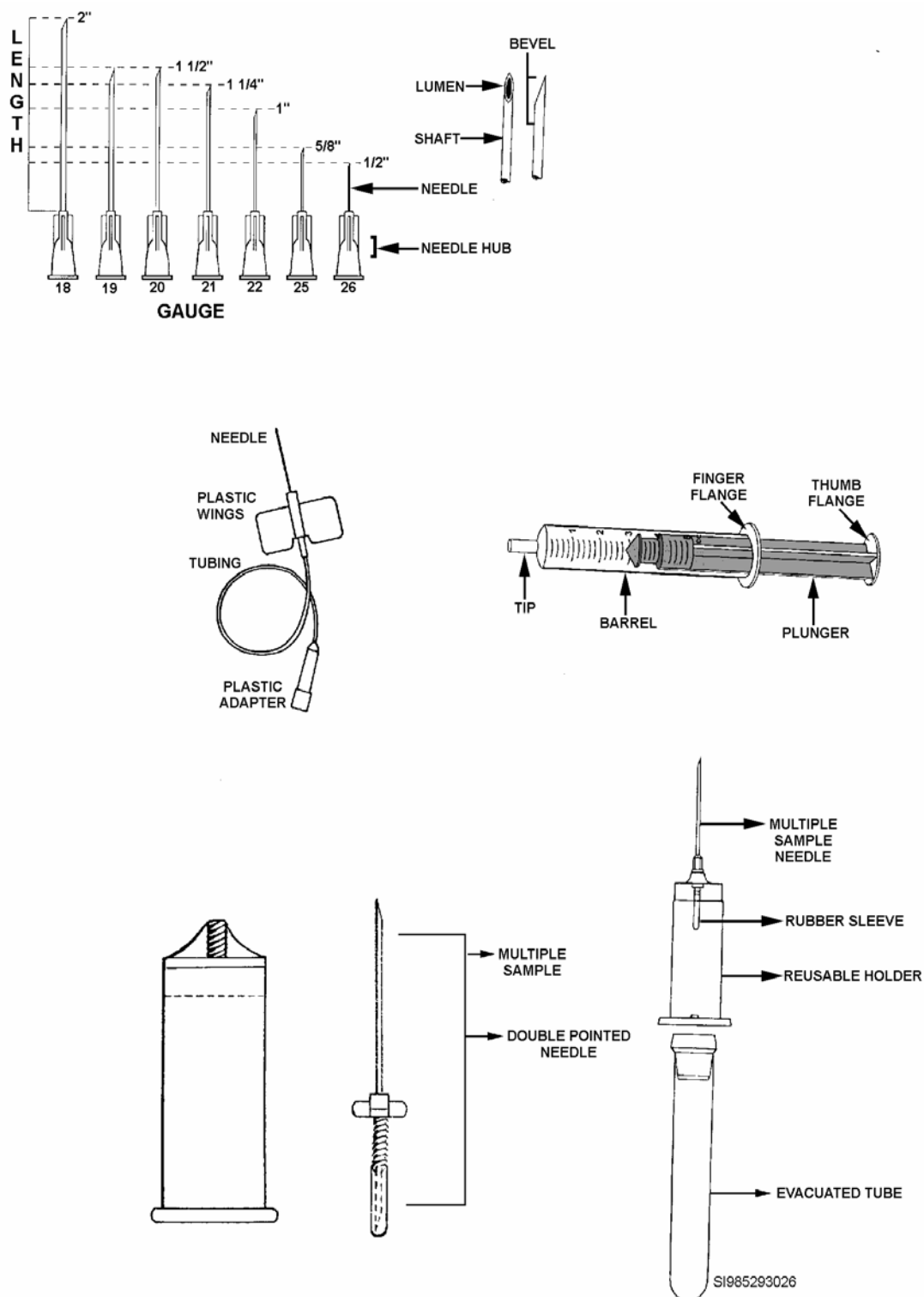


Figure 4-1. Examples of venipuncture equipment.

A butterfly needle

A butterfly or winged infusion set is excellent for collecting blood from infants, children, and elderly patients with fragile or difficult veins. It consists of a 25- or 23-gauge stainless-steel needle with a plastic-winged extension and 5- or 12-inch-length tubing (fig. 4-1). The butterfly can be attached directly to a syringe or an evacuated tube holder by means of a Luer adapter.

Evacuated tube system

The evacuated tube system is comprised of a single or multi-draw sample needle, reusable plastic holder, and evacuated blood tubes (fig. 4-1). Single and multi-draw sample needles come in 19, 20, 21, and 22 gauges, with a 20 or 21 gauge used most often for routine venipunctures. These needles have threaded middle portions and a bevel point at both ends. The threaded portion securely attaches to the holder. One end of the needle enters the patient's vein and the other end penetrates the evacuated tube's rubber stopper. On the multi-draw needle, a rubber sleeve over the end inside the holder is actually the part that allows this to be a multi-draw system. Once an evacuated tube is removed, the rubber sleeve moves back into place and prevents the leakage of blood. If the sleeve is defective or pops off completely, you have a "bloody mess" (as some say) literally. Be aware that this occasionally happens and can be distressing for the patient. Be prepared to deal with this situation efficiently.

Evacuated tubes for whole blood, plasma, and serum specimens

Once blood leaves the body, it naturally begins to clot. This is fine if serum is required for testing, but it is difficult to count red blood cells (RBC) and white blood cells (WBC) in coagulated blood. Because some procedures demand whole blood or plasma, you must mix the blood with an anticoagulant in order to prevent clotting. The choice of anticoagulant depends on the test method. It is important to remember that an appropriate ratio of anticoagulant to blood is critical to prevent sample dilution as significant errors may result with incorrect anticoagulant concentrations. The tubes are evacuated to hold the exact amount of blood needed for the proper ratio. If the blood tube isn't allowed to fill completely (e.g., because it was pulled out too soon), there will be too much anticoagulant in the specimen. This can cause changes in cell sizes and morphology. If the tube is overfilled, the decrease in anticoagulant may cause clots. Let's look at some of the most commonly used collection tubes.

Red-top or clot tubes

Red-top or clot tubes have no additives and are used for serum. They are sterile, empty tubes or contain clot enhancers or activators. Some have a gel polymer for serum and cell separation. The color or design (tiger-top) of the red-top tube depends on the type of activator or gel in the tube.

Ethylenediaminetetraacetic acid

Ethylenediaminetetraacetic acid (EDTA) is found in two forms: disodium and tripotassium salts. EDTA is an excellent anticoagulant that either chelates or binds calcium ions. Tripotassium EDTA is the anticoagulant of choice because it is in liquid form and, therefore, goes into solution easier. At a concentration of 1.5 milligrams per milliliter (mg/ml) blood, EDTA prevents artifacts and preserves cellular morphology when blood films are made within 2 hours. Blood can be stored for 24 hours at 4 to 6°C without changing hemoglobin, hematocrit, leukocyte count or WBC or RBC count, though you may see artifacts and WBC morphology (i.e., reactive lymphocytes, degenerated neutrophils) and RBC morphology (i.e., pyknotic nucleus) changes. EDTA prevents platelet clumping but cannot be used for platelet function studies. In concentrations above 2 mg/ml blood, RBCs shrink and cause sedimentation and hematocrit values to be falsely decreased. EDTA inhibits the following tests: alkaline phosphatase, creatine kinase, or leucine aminopeptidase. Because of chelating, we can not use it for calcium or iron testing.

Citrate

The anticoagulant of choice for coagulation studies is trisodium citrate. Coagulation is prevented by binding calcium in a soluble complex, protecting most labile clotting factors. Proper concentration is 1 part 0.109 M (3.2%) buffered sodium citrate to 9 parts blood. Citrate tubes must be adjusted for hematocrits <20% and >55% because the 9:1 ratio of blood to anticoagulant is critical.

Heparin

This anticoagulant prevents clot formation by neutralizing thrombin when mixed at a concentration of 15 to 20 units per milliliter (U/ml) of blood. Heparin is the anticoagulant of choice for osmotic fragility tests. It is unsatisfactory for automated cell counters and for making blood films (due to distortion of platelets and leukocytes). It must never be used for coagulation studies because it inhibits thrombin. It is the anticoagulant of choice for most chemistry analyses and may be used for STATs.

Sodium fluoride

Sodium fluoride is used mainly for glucose levels. Fluoride interferes with many serum enzymes. It functions by interfering with glycolysis (breaking down of sugar), and for this reason, it is used for glucose testing and is considered to be a preservative more than an anticoagulant. Sodium fluoride does have weak anticoagulant properties and is often mixed with potassium oxalate to increase its effectiveness as an anticoagulant. Specimens drawn using sodium fluoride may be stored at 25°C for 24 hours or at 4°C for 48 hours, without a significant decrease in the glucose level. Sodium fluoride doesn't dissolve well, so you must thoroughly mix it after collection.

Oxalates

Oxalate anticoagulants come in several different forms: ammonium, lithium, potassium, and sodium. Oxalates function by forming an insoluble complex with calcium. This process inhibits coagulation. One of the more commonly used oxalates was double oxalate. Double oxalate is the term used for a mixture of *ammonium oxalate* and *potassium oxalate*. Double oxalate was used primarily in hematology, but it has been replaced by the more popular EDTA. The primary disadvantage of double oxalate is its inability to maintain normal cell morphology due to the exchange of fluids within the cells. Another disadvantage is that it causes hemolysis in high concentrations.

Evacuated tube color coding

For easy identification of evacuated tubes, the rubber stopper is color-coded. The color represents the anticoagulant or clotting activator within the tube. The table below presents a review of the most commonly used tubes for blood collection.

Color	Anticoagulant	Section	Determination
Brown	Sodium heparin	Chemistry, Shipping	Lead levels
Dark Blue	Sodium heparin	Chemistry, Hematology, Special Chemistry, Shipping	Trace elements, toxicology, and nutrient determinations
Gray	Sodium fluoride	Chemistry, Special Chemistry, or Shipping	Glucose tolerance test
Green	Ammonium, lithium, or sodium heparin	Chemistry, Hematology, Special Chemistry, Shipping	Chemical analyses
Lavender	Liquid K ₃ EDTA, Freeze-dried Na ₂ EDTA	Hematology	Complete blood counts, differentials, and ESR
Light Blue	Sodium citrate	Coagulation	PT, PTT, and other coagulation studies
Red	No anticoagulant	Blood Bank	Blood typing, cross-matches, antibody and antigen studies
Red combination	Clot activators or gel	Chemistry, Immunology,	Antibody and antigen studies,

Color	Anticoagulant	Section	Determination
"Tiger-top"		Special Chemistry, Shipping	chemical analyses
Yellow— Large tubes	Sodium polyanetholsulfonate (SPS)	Microbiology	Blood cultures
Yellow— Small tubes	Acid Citrate Dextrose	Immunology, Shipping	HLA tissue typing

Collection order

In many cases, policies have been established that dictate the order of draw for evacuated tubes. This prevents cross-contamination of anticoagulants or tubes containing media (blood culture). Usually, blood cultures are drawn first, then clot tubes. This is followed by citrate tubes for coagulation, heparin, EDTA, then oxalate and fluoride tubes.

NOTE: Because of tissue thromboplastin from the initial puncture, if only coagulation tests are ordered, first collect a small amount of blood in a clot tube (to be discarded) followed by the citrate tube. Now that you have your tube order and venipuncture equipment organized, it's time to collect the blood sample. Blood withdrawn by syringe is handled differently—consult your laboratory OIs for more information.

014. Blood collection by venipuncture

The individual who develops a never-fail, vein-finding apparatus will most likely win the Nobel Prize and live forever in the hearts of men and women everywhere! However, you already know that most experts have developed their own technique through years of trial and error. Collecting a proper specimen is the first step toward reporting accurate and reliable test results. This entails proper patient identification and technique.

Patient identification

Whether the specimen is acquired in the lab, clinic, or ward, correct patient identification is essential. Before drawing the blood sample, you must positively identify the patient. For an inpatient, you do this by comparing the request form with the information on the patient's identification or armband. Don't rely on a bed tag, on charts, or on records placed nearby. If the patient is unconscious or comatose and there is no identification band, have a nurse identify the patient. If the patient is ambulatory or an outpatient (without an armband), check his or her ID card, ask him or her to state his or her name and SSN, or have him or her visually verify the information on the request form. *Don't* ask yes or no questions such as the following, "Are you MSgt Peter Gunn?" An ill or semiconscious person may mistakenly answer incorrectly. If the patient is too young, mentally incompetent, or doesn't speak the language of the phlebotomist, ask the patient's nurse, relative, or friend to identify the patient.

After identification

After properly identifying the patient, remember to reassure him or her. Make the patient as comfortable as possible. Talk to him or her calmly and professionally in order to gain his or her confidence. Briefly review the procedure and tell him or her that it is slightly painful. Don't lie to the patient by saying it doesn't hurt. No one likes to be deceived. Annotate patient posture position on the requisition form due to changes in some analytes or blood counts.

NOTE: If the patient inquires about the test being done, don't tell or inform him or her about the procedure(s). Leave this to the physician. Remind the patient to speak with his or her physician about the procedures.

The venipuncture

The requisition form has been verified, the patient has been identified and reassured, and supplies and equipment are assembled. It is time to begin the venipuncture.

Layers of the skin

Before moving to the venipuncture procedure and skin puncture site selection, let's look beneath the surface of the skin. This will give you an idea of where the needle or lancet is destined during the puncture. A term with which you must be familiar is "parenteral." This term is used occasionally in these CDCs. A simple definition for parenteral administration is injection of an illicit drug, infectious agent (accidentally), unit of blood, or medication through a needle or infusing through a catheter. Venipuncture is opposite from parenteral in that it removes fluid instead of administers fluid, but it is the same because we also break the skin barrier.

Parenteral injections

Advantages to parenteral injections are medications are absorbed rapidly into the circulatory system; medications are almost totally absorbed (oral medications may be partially destroyed by the digestive system); and parenteral administration allows drugs to be given to patients who cannot or will not swallow, such as patients who are unconscious or uncooperative. Unfortunately, there are some major disadvantages and hazards associated with parenteral administration of medications. The external skin barrier is compromised during injection and vascular infusion. Because parenteral administration involves penetrating the body abnormally, the risk of possible nerve damage, tissue necrosis, infection, abscess, and pain increases.

Methods of administering drugs

There are several different methods of administering drugs and solutions parenterally. The most common methods are intradermal injection, subcutaneous injection, intramuscular injection, and intravenous injection. Intradermal injections are made between the layers of the skin, specifically the epidermis and dermis, as shown in figure 4-2,A. Subcutaneous injections are made in the subcutaneous tissues between the dermis and muscle (fig. 4-2,B). Intramuscular injections are made through the skin and subcutaneous tissue, directly into the "meat" of a large muscle group (fig. 4-2,C). Since muscle is highly vascular tissue, medication absorption is rapid. Intravenous injection or infusion involves administering the medication directly into a vein (fig. 4-2,D) to achieve the most rapid, nearly immediate, effect. As you can see from the figure, when you insert a needle for venipuncture, you are going through various layers of tissue. These layers contain small capillaries, nerves, and muscles. This is one reason for the pain and discomfort. It is very important to select the appropriate site so that you don't have to dig or move the needle around to find a vein.

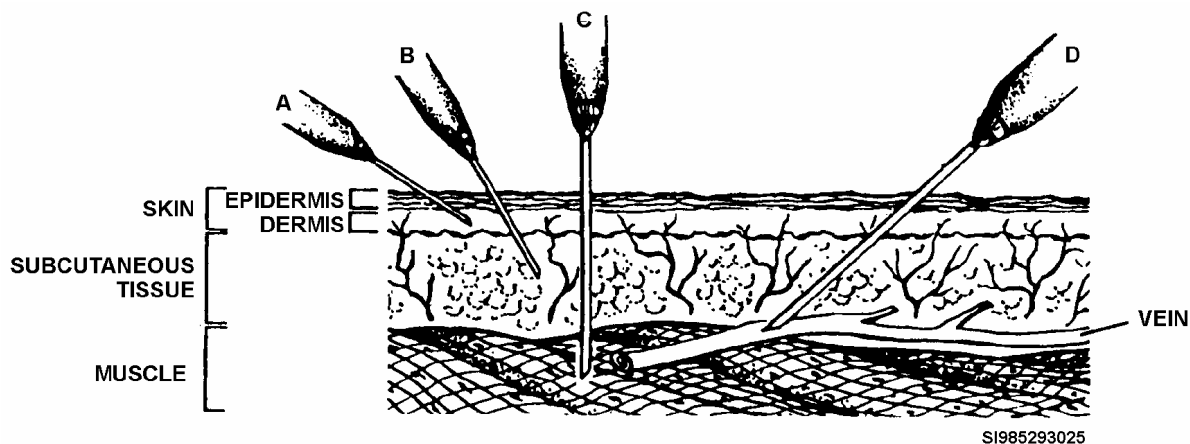


Figure 4-2. Methods of parenteral administration via injection.

Selecting the site

First, securely apply the tourniquet 3 to 4 inches above the intended venipuncture site. Ask the patient to make a fist; this increases venous filling, which makes the veins visible. A well-filled vein is easy to enter with minimal trauma. If the patient's arm feels cold, warm towels or gentle massaging may help bring veins into view. The three major veins in the arm we use for venipuncture are the cephalic, basilic, and median cubital veins, as shown in figure 4-3. The median cubital vein is the preferred site because it is close to the skin surface, it is large, and it is surrounded by tissue that anchors it—preventing the vein from rolling (moving away). You can use the other two veins, but they tend to roll and bruise easily. If you cannot locate a distended vein, try to find a deep vein through palpation. If this doesn't provide possibilities, look at the forearm, wrist, and top of the hand, as shown in figure 4-4. You can use an ankle or foot but only if you consult a nurse or physician first. There are clinical conditions that could make this dangerous for the patient (e.g., circulatory problems in lower extremities, diabetes in poor control, hemoglobinopathies, and edema). Although, as you know, some of these areas can be quite uncomfortable for the patient, your skill can minimize the pain. In any case, you must find the best possible site, without probing, so that you can insert the needle without causing tissue trauma, bruising, or pain. If you cannot locate a site, a physician may elect to draw from the jugular vein, femoral vein, or one of the larger arteries. Absolutely under no circumstances do you ever use these veins.

NOTE: Don't leave the tourniquet in place for more than 1 minute; this may cause an abnormal blood dilution or concentration. You may need to release the tourniquet for a little while and then try again. Also, avoid areas with hematomas, edema, burns, or scars; and avoid the arm on the side of a mastectomy.

Special venipuncture considerations:

Patients that have undergone mastectomies will typically have lymphostasis (no lymph flow) due to removal of lymph nodes in proximity to the breast tissue because of the surgery. Lymphostasis places the patient at a higher risk of infection in that body part and may concentrate blood constituents creating erroneous laboratory results. The pressure from the tourniquet may potentially cause injury to these patients. Consult the patient's provider before drawing blood from patients that have undergone double mastectomy. Typically, the blood will be drawn from the side of the first surgery. The bottom line is to **never** draw blood from an arm that is on the same side as a mastectomy without consultation and approval from the patient's provider. If after consultation the provider approves the venipuncture from the same side as a mastectomy always ensure that you annotate this approval with as much detail as possible before reporting results.

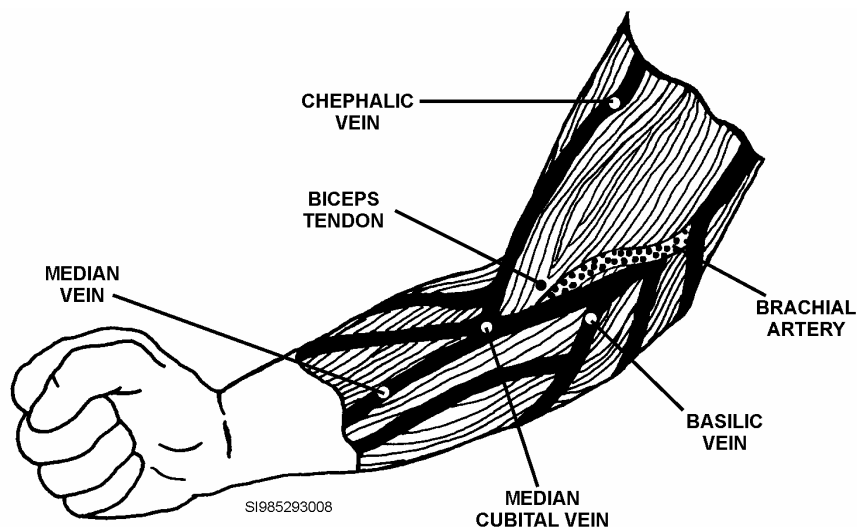


Figure 4-3. Veins of the arm.

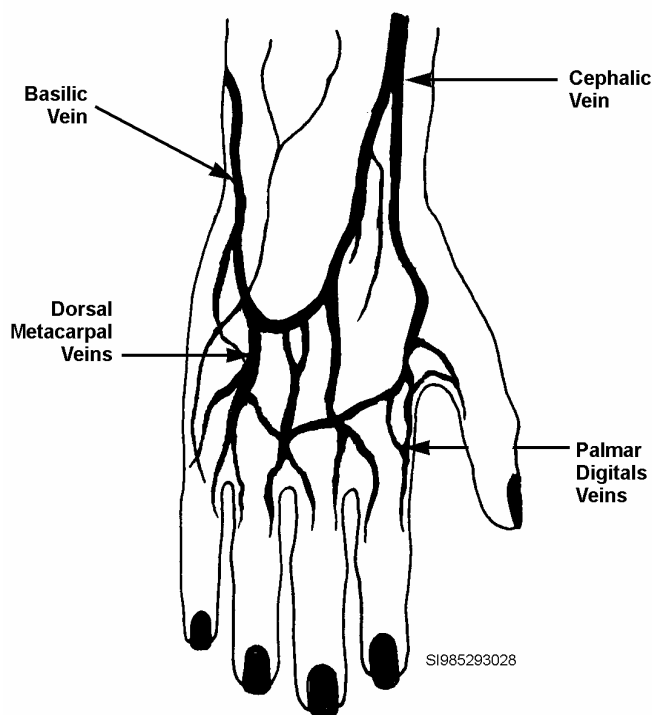


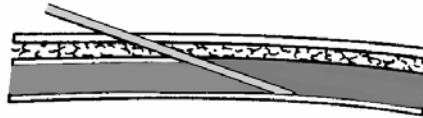
Figure 4-4. Veins in the hand.

Preparing the site

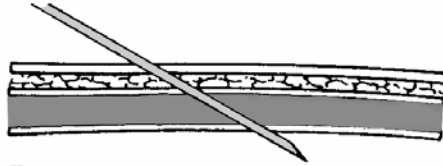
Once you locate the site for venipuncture, cleanse and prepare the area before needle insertion. The best all-around cleansing agent is 70% isopropyl alcohol. Although it does not create sterility, it removes body oils and surface dirt adequately. Clean the site by vigorously rubbing the area in a circular-type motion, moving from the inside to the outside. Allow the area to dry because the alcohol can cause burning at the entry site and may contaminate the blood and cause hemolysis. If you need to touch the area again for any reason, you must reclean the site. Three exceptions exist to the use of alcohol for site preparation: drawing blood for alcohol determinations, bacterial cultures, and blood donations. Use a nonalcoholic disinfectant for blood alcohol determinations. Blood cultures and blood donations require a sterile phlebotomy site.

Performing the “stick”

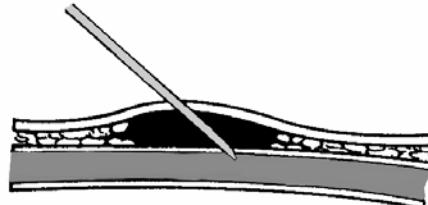
After cleansing the area and while it is air-drying, remove the cap of the needle and inspect it. You are looking at the tip for hooks, obstructions, or other defects. If the needle has no defects, anchor the patient's vein by pulling the skin taut with your thumb as you grasp the arm with the fingers. Ensure the bevel of the needle is facing upward. Views A through E in figure 4-5 show examples of improper bevel alignment. Enter the vein in a deliberate, smooth motion. When using an evacuated tube system, firmly hold the needle in place while changing tubes. Once the tube is in place and it starts to fill, ask the patient to open his or her fist and then loosen the tourniquet. By inversion, gently mix anticoagulant tubes immediately. If you are using a syringe, the steps are the same, but avoid pulling on the plunger forcefully since this can cause hemolysis or collapse the vein. Don't ever force blood into a tube from the syringe needle—this can cause hemolysis. If the vein is difficult to enter or a hematoma begins to form, remove the tourniquet and then promptly remove the needle. Don't apply a tourniquet to this site again for at least 20 minutes. This allows the puncture area to heal. If multiple venipunctures are required for a tolerance test, use several different sites to avoid pain and bruising of the same site.



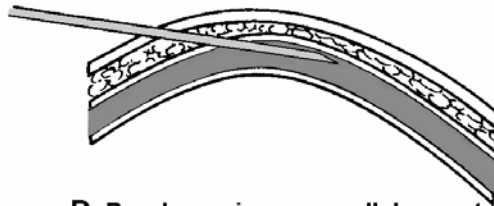
A. Bevel on vein lower wall does not allow blood to flow.



B. Needle inserted too far.



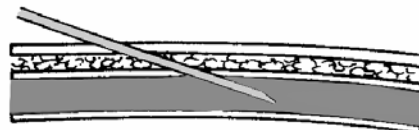
C. Needle partially inserted and causes blood leakage into tissue.



D. Bevel on vein upper wall does not allow blood to flow.



E. Collapsed.



F. Correct insertion technique; blood flows freely into needle.

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Figure 4-5. Improper bevel alignment venipuncture problems.

Finishing the “stick”

When you collect all the required tubes, completely release the tourniquet and without pressure, place gauze over the needle, and then quickly, but gently, pull out the needle. Immediately apply pressure to the site. Instruct the patient to hold direct pressure on the site for at least 3 to 5 minutes and to hold his or her arm straight out. Bending the arm can cause the wound to reopen, which may result in a hematoma. Also, check the patient’s rolled-up sleeve to ensure that it isn’t too tight, thereby acting as a tourniquet. To further enhance the effectiveness of direct pressure, the patient can elevate his or her arm above the heart. Give the patient a bandage for later application, if needed.

Discarding the needle

Immediately after the venipuncture, dispose of the needle in a proper container specifically made for needles and sharp instruments and labeled as “biohazard.” An example is shown in figure 4–6. *Never* place a needle in a regular wastebasket or anything other than a sharps container.

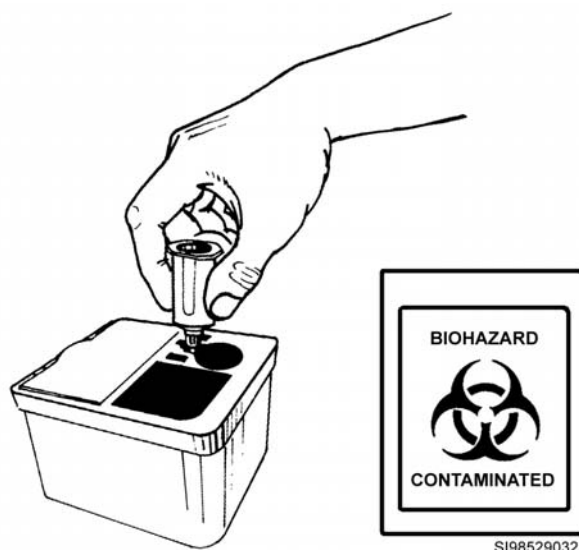


Figure 4–6. Example of a sharps container.

Labeling the specimen

After collecting the sample and before leaving the bedside or side of the patient, you must label the blood sample tubes with the patient’s first and last names, ID number or SSN, the date and time of collection, and your initials. You can use imprinted or computer labels if the information on the label is identical to that on the wristband and request form. Release the ambulatory patient and thank him or her. Before leaving an inpatient’s room, check to ensure that all supplies and equipment are cleaned up and removed from the area. If a bed rail was lowered to do the venipuncture, guarantee it is put back up securely into place, and thank the patient.

Special considerations

As you studied earlier in this volume, the age-specific guidelines in the following table also apply regarding venipuncture.

Age-Specific Guidelines	
Life Stage	Lab Interaction and Concerns
Neonate/infant (≈ birth to 1 year)	Provide as much comfort as possible during the procedure. Venipuncture (when required may be exceedingly difficult)—do your absolute best to minimize trauma and multiple sticks. Use a syringe and smallest-bore/highest-gauge needle as appropriate.
Toddler	Provide as much comfort as possible during the procedure. Answer any questions

Age-Specific Guidelines	
Life Stage	Lab Interaction and Concerns
(≈ 1 to 3 years)	honestly, but with a minimum of extra explanation.
Childhood/preadolescent (≈ 3 to 12 years)	Provide as much comfort as possible during the procedure. You can provide more detailed explanations of the procedure. Patient may show more interest in the procedure and be more inquisitive as to what he or she can expect than a patient at the toddler stage.
Adolescent (≈ 12 to 19 years)	Be sensitive of patient's feelings regarding collection and delivery of specimens of an excretory and/or secretory nature.
Early adulthood (≈ 19 to 40 years)	Be sensitive to fertility studies; fertility and sexually transmitted diseases (STD) results and the delivery of stool and semen specimens.
Late adulthood (≈ 40 to 65 years)	Health concerns increase among this age group. Be sensitive to specimen delivery of stool samples and occult blood specimens.
Geriatric (≈ 65+ years)	Veins may be frail and difficult to locate and use. Syringe use may be the most appropriate method.

Pediatric

Only the most experienced technician should attempt to draw a child under the age of 2 years old. The technique is the same, but the small veins necessitate the use of small-bore needles or a winged transfusion set. Be careful when using a small-bore needle; slowly pull back the syringe plunger. This helps to ensure a nonhemolyzed specimen. Also, only use superficial veins. NCCLS recommends the use of a 3 ml or tuberculin syringe with a 21- or 23-gauge needle.

Adolescents

Keep in mind that adolescents aren't adults or infants. They may have good veins or difficult veins. They can be just as frightened as young children, but they want to be treated as adults. Walk them through the procedure and prepare them for the slight pain. Adolescent veins can collapse easily—be gentle.

Geriatric or elderly

When drawing blood from an elderly patient, detached and floating veins can cause difficulty. These veins are quite often soft and collapse easily. Anchor the vein both above and below the venipuncture site. If you feel an evacuated tube system might collapse the vein, use a syringe and pull the plunger slowly and gently. Remember, older patients often bruise easily; be as gentle as possible and strictly apply direct pressure.

Intravenous infusions

If blood is to be drawn from a patient with an intravenous (IV) infusion, draw from the opposite arm if at all possible. If you must draw from the IV arm, close the infusion set or stop the flow of fluid for at least 2 minutes before performing the venipuncture. Place the tourniquet below the IV site. Select a vein *below* and *different* from the one with the IV. Carefully perform the venipuncture. Draw approximately 5 ml of blood and discard it before drawing the other tubes.

Mixing specimens

Don't forget to thoroughly mix the blood and anticoagulant. Few experiences are as embarrassing as calling a patient for a repeat venipuncture because of clots in anticoagulated tubes. Murphy's law dictates that the harder the specimen was to draw, the easier it clots. Hence, this causes the patient to endure additional discomfort and pain. Take the extra few seconds to ensure proper mixing; it's well worth the effort.

Adverse patient reactions

Constantly be aware of the patient's actions and condition. Various adverse patient reactions can occur before, during, or after venipuncture. The reactions include dizziness, fainting (syncope),

nausea, vomiting, and convulsions. If the patient has one or more of these reactions, remove the tourniquet and needle immediately. Have the dizzy patient lower his or her head and arms if sitting. If the patient faints, carefully lower him or her to the floor, loosen tight clothing, administer an ammonia inhalant, and once he or she regains consciousness, apply cold compresses to the forehead and back of the neck if necessary. Notify emergency personnel and a physician if the patient doesn't respond. For the nauseous patient, make him or her as comfortable as possible, instruct him or her to breathe deeply and slowly, and apply cold compresses to his or her forehead. If the patient is vomiting, give him or her an emesis basin or any type of carton (e.g., trash can), have tissues ready, and give the patient water to rinse out his or her mouth. Report the incident to nursing personnel. For the patient who is having convulsions—scream for help—and prevent the patient from injuring himself or herself. Move the patient easily and quickly to the floor. Don't hold the patient's extremities too tight, but keep them from being injured.

015. Blood collection by skin puncture

Your skill and technique in performing skin puncture collections is important. Why? The reason is simple; usually the better you are, the less traumatic and the less severe the experience is for the patient.

The purpose of a skin puncture

For infants under 3 months of age, skin puncture is the technique of choice for blood collection. Puncturing deep veins in children this young can cause cardiac arrest, venous hemorrhage, venous thrombosis, reflex arteriospasm, gangrene of an extremity, damage to surrounding tissues, or infection. Also, the infant may be injured while being restrained for the procedure.

Standard precautions

Remember to treat all blood specimens, whether from children or adults, as though they might be infectious. With skin punctures, the blood isn't neatly contained in a closed system; therefore, exposure is greater.

The skin puncture

You can use skin puncture on infants, young and older children, young adults, adults, and the elderly. This technique is very useful in drawing from severely burned patients, extremely obese patients, geriatric patients, and patients who don't have usable veins.

Organizing equipment

Skin puncture supplies and equipment include gloves, sterile gauze, heel warmer or warm, moist towel, alcohol pads, bandages, capillary tubes, capillary tube sealant, microcollection tubes, volume pipettes for the Unopette system, glass slides, and possibly filter paper (PKUs) or reagent strips (glucose). We cover the Unopette system and the procedure for preparing differential slides later.

Capillary tubes

Capillary tubes come in different bore sizes and volumes or capacities. They can be heparinized or nonheparinized. The small-bore capillary tubes, also known as microhematocrit tubes, hold approximately 50 to 75 microliters (μl) of blood. A red band at one end of the tube indicates an ammonium heparin-coated tube, and a blue band indicates a plain tube. The large-bore tubes, known as Caraway or Natelson tubes, can hold approximately 250 μl of blood and are tapered at one end. A yellow band at the nontapered end indicates a lithium heparin-coated tube; nonanticoagulated tubes also have a blue band.

Microcollection tubes

Microcollection tubes are made of plastic and have color-coded stoppers that indicate the type of anticoagulant. The color coding corresponds to the evacuated tubes. To illustrate, lavender-top tubes

contain EDTA, red-top tubes are plain (no additive), and so on. Use the tubes with the collector top for collecting free-flowing blood and then “cap” them for transport.

Selecting the site

The possible sites for collecting capillary blood are the lateral or medial plantar surface of the infant’s heel, plantar surface of the big toe, and palmar surface of the distal phalanx of a finger, as shown in the shaded area in figure 4-7,A.

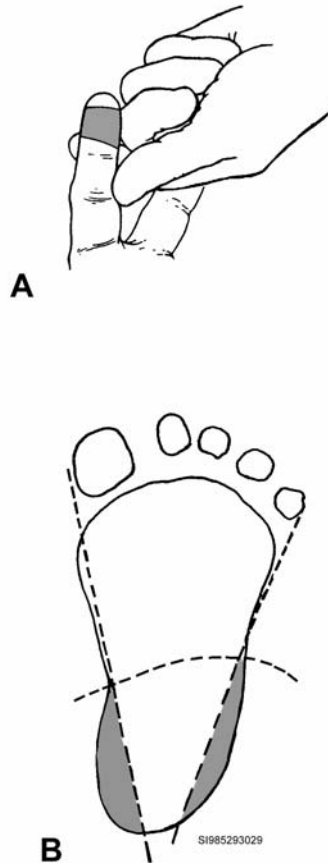


Figure 4-7. Sites for skin puncture.

Infant’s heel

If blood is to be drawn from an infant’s heel, pick a site on the edge of the heel. Such a site you can locate by drawing a line from the great toe to the heel or from between the fourth and fifth toes to the heel, as shown in the shaded area in figure 4-7,B. Don’t use the end point of the heel or the central area (arch) of the foot. The end point can be as close as 2.4 millimeters (mm) from the bone. The arch has a lot of nerves, tendons, and cartilage. Before beginning a heel puncture on an infant, take time to examine both heels for excessive wound marks. If you find considerable numbers of wounds, show the areas to the charge nurse and notify the laboratory supervisor. This could possibly save the laboratory future embarrassment, and it may also notify nursing personnel of their need for further training. In newborns, the heel is most often cool; warm it before you do a skin puncture.

Big toes

You can use a big toe if the fingers on a child are too small. Follow the same finger stick procedure.

Finger

Never do a finger stick on an infant. The distance from the skin to the bone varies from 1.2 to 2.2 mm. With the available lancets, you could easily injure the bone. Local infection and gangrene are also potential complications from infant finger sticks. In older children and adults, you can use the fleshy surface of the distal phalanx (last joint) of the index, middle, or ring finger or thumb. Don't use the fifth or pinkie finger because it is too thin. Don't make the skin puncture on the side or tip of the finger; the tissue in these areas is half as thick as in the center area. If the site you've selected is cool to the touch, warm the area with a moist towel for about 3 minutes at a temperature of 42°C. The moist heat encourages circulation without burning the patient. Don't use a swollen finger (edematous) because of the higher concentration of tissue fluid.

Preparing the site

Site preparation for skin puncture is quick and uniform for all sites. Cleanse the area with 70% isopropyl alcohol. Be sure to remove all of the alcohol from the site since this causes immediate specimen hemolysis and can possibly affect glucose determinations.

Performing the stick

Blood obtained by puncturing the skin is a mixture of blood from arterioles, venules, and capillaries, as well as interstitial and intracellular fluids. The specimen is more closely related to arterial blood because the pressure in the arterial limb of the capillary is greater than the pressure in the venous limb. For this reason, you can see differences in some analyses. It is important to label the patient's slip as a skin puncture.

Heel stick

Once you select and clean the heel puncture site, grasp the foot firmly without using the leg for leverage. Without hesitation, in order to minimize trauma, puncture the edge of the heel once with a suitable lancet. Don't use double punctures such as Ts or Xs, or the like, or scalpel blades for heel punctures. A single, well-placed lancet wound provides ample blood. Wipe away the first drop of blood; this may contain tissue fluids. Then collect the rest of the sample as free-flowing blood into capillary tubes or through the collector top of a microcollection device. Mix anticoagulated tubes by inverting them 8 to 10 times. When the collection is complete, place clean gauze firmly on the site, elevate the foot, and apply pressure until the bleeding stops. Do not apply bandages and then leave the patient. A young child may remove the bandage and place it in his or her mouth, which could result in choking. Also, before leaving the infant's bedside, check for laboratory equipment. Be certain you do not leave behind any materials that may harm or cause injury to the patient.

Finger stick

To perform a skin puncture on older children and adults, cleanse the site, dry it, and do the puncture quickly. Once again, a single puncture is enough to yield a sufficient sample. Wipe away the first drop and collect the free-flowing blood, as shown in figure 4-8. Mix anticoagulated tubes by inverting them 8 to 10 times. As before, place clean gauze on the site; then have the patient hold pressure until the bleeding stops. Always keep in mind that a skin puncture hurts, so be compassionate.

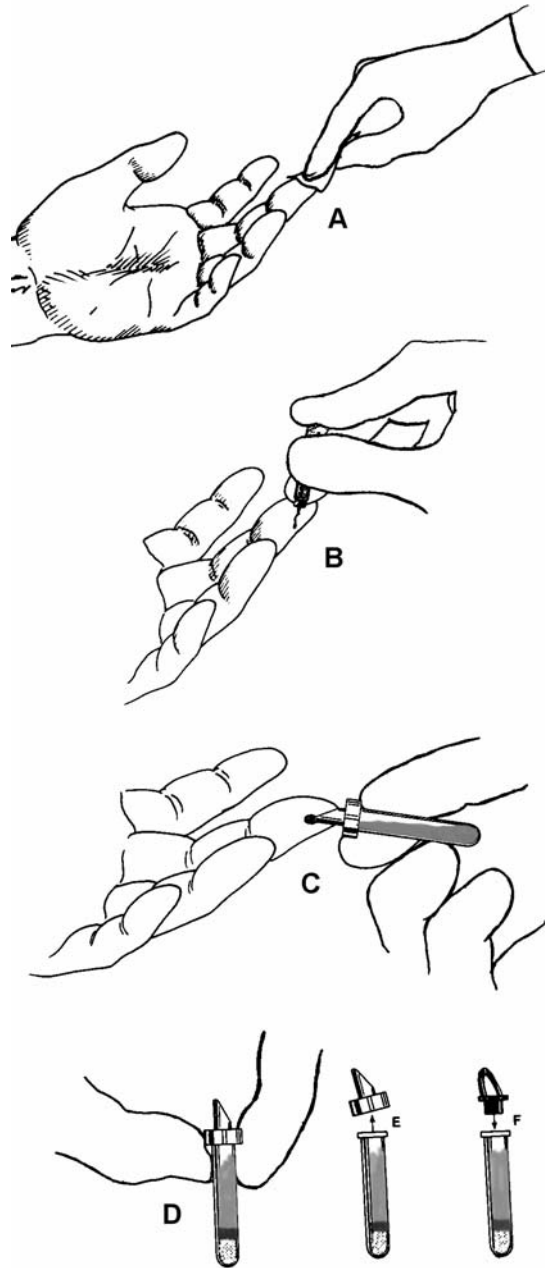


Figure 4-8. Example of the blood collection technique from a finger stick.

Sealing capillary tubes

Seal capillary tubes with sealing clay or specially made covers. Carefully place the tube in sealing clay to avoid breaking the tube.

Disposing of lancet

Dispose of lancets in rigid puncture-resistant containers (sharps container) clearly marked as biohazardous.

Labeling the specimens

Label all microcollection devices individually immediately following collection and mixing. Capillary tubes are very difficult to label, so you can place them in a sterile red-top tube or another

container. Label this tube or container with the required information (last name, first name, SSN, date and time, and collector's initials).

Special considerations

Don't milk or use strong repetitive pressure on heels, toes, or fingers; this can cause hemolysis or contamination with tissue fluid. Avoid scooping blood from the surface of the skin, where it has run down the heel or finger. If a drop of blood becomes lodged in the collector top or on the side of the tube, gently tap the tube on a hard surface (avoid splatters); the blood should move to the bottom of the tube.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

013. Patient instructions and equipment preparation

1. What is the very first step in specimen collection, and who initiates it?
2. What type of information can you find on the request form?
3. How should patient instructions be written?
4. List the supplies and equipment required to do a venipuncture.
5. What is the bore size or gauge of a needle, and what does a small and large gauge mean?
6. What do you consider when choosing needle size?
7. Who are syringe systems used for?
8. What needle size or gauge do you use when transferring specimens from syringes to evacuated tubes?
9. Who are winged infusion sets used for?
10. Why do you use anticoagulants?

11. Fill in the missing information about color-coding evacuated tubes.

Color	Anticoagulant	Section	Determination
Brown			
Dark blue			
Gray			
Green			
Lavender			
Light blue			
Red			
Red combination "Tiger-top"			
Yellow— Large tubes			
Yellow— Small tubes			

12. Why is it important to establish a collection order? List the order.

014. Blood collection by venipuncture

1. How do you positively identify an inpatient?
2. How do you positively identify an ambulatory or outpatient?
3. Where do you apply the tourniquet for a venipuncture?
4. Which vein is preferred and why?
5. When can you draw from an ankle or foot and what conditions make this dangerous?
6. How long can you leave a tourniquet on and what areas do you avoid?

7. What are the three exceptions for the use of 70% isopropyl alcohol?
8. What do you inspect the needle for?
9. Why do you tell the patient not to bend his or her arm after a venipuncture?
10. After collecting the sample and before leaving the bedside or side of the patient, what must you do?
11. What does NCCLS recommend using for drawing specimens from children under the age of 2?
12. How do you anchor a vein in the elderly and why?
13. If a patient faints during a venipuncture, what do you do?

015. Blood collection by skin puncture

1. Why is skin puncture the technique of choice for blood collection for infants under 3 months of age?
2. On whom and for what reason can you use skin punctures?
3. List the supplies and equipment used for skin punctures.
4. How much blood does a capillary tube hold, and how can you tell the plain from the anticoagulated tubes?
5. How much blood does a Caraway or Natelson tube hold, and how can you tell the plain from the anticoagulated tubes?

6. Where are the ideal spots from which you draw blood from an infant's heel?
7. Why do you not draw blood from the end point or arch of the infant's heel?
8. What site do you use for a finger stick and which fingers do you use?
9. Why do you wipe away the first drop of blood from a skin puncture?
10. How can you release a drop of blood that becomes lodged in the collector cap of a microcollection tube?

4-2. Specimen Processing and Medical Terminology

Appropriate handling throughout the entire collection process, including transportation and processing, is important for preserving specimen integrity, as well as for protecting laboratory personnel from hazards. This section reviews key elements in specimen processing. We also introduce you to the special language of the health-care profession—medical terminology.

016. Specimen processing

Drawing the blood specimen is a major step, but if the specimen is improperly processed, it isn't reliable for analysis. You must pay close attention to the details of specimen processing. It can be very embarrassing to recall a patient for redrawing because of a processing error; the laboratory looks incompetent.

Transport of specimen

Transport specimens to the laboratory or the section performing the tests as soon as possible. Keep the tubes upright or vertical because this promotes complete clot formation and reduces agitation, which in-turn reduces hemolysis. In some instances, depending on testing, a specimen requires special handling while in transit. An example of this would be a specimen for a blood gas determination. Blood gas specimens must be kept in a container containing a slurry of crushed ice and water, and they must be analyzed as soon as possible. If they are not, cell metabolism continues. The $p\text{CO}_2$, $p\text{O}_2$, and blood pH will be affected because of improper handling. Another example of special handling involves minimizing light exposure, which must be avoided for vitamin A, vitamin B6, bilirubin (newborn) testing, for example. If you are unsure how to transport or handle a specimen, check your laboratory OI and/or guide. How a specimen was transported or handled is sometimes out of the laboratory's control if that specimen is drawn by other MTF personnel. When you receive a specimen, ask yourself the following questions:

- Has the proper container been used?
- Has the specimen been refrigerated?
- If it was frozen, has it thawed?
- Has the proper transmittal paperwork accompanied the specimen?

Here again, you can think of many more questions, but what is important is that you are aware of the factors involved in specimen transportation.

Laboratory numbering

Each specimen received or collected by the laboratory is given a laboratory number with the date and time annotated. This is done through the computer system when the patient checks in at the laboratory front desk. Always verify the correct patient by using his or her ID card. Up to this point, the request by the physician is unacknowledged. Once acknowledged by the laboratory, at time of patient check-in, a section-specific or section-designated number is assigned. It is critical that the patient's specimen be labeled correctly. Clerical errors are the hardest errors to detect and are usually the most common error made in a clinical laboratory. Pay special attention when accessioning specimens. If the test ordered requires special handling, be sure to add any appropriate labels. Remember, handle all specimens as if they were infectious. This will protect you from any contagions while you handle the specimen during processing.

Specimen rejection

In certain instances, you may have to reject a specimen. Always consider this carefully. In some cases, it may be a specimen that was difficult to collect, such as a spinal fluid, and you do not want to just dismiss it. Do what you can to make the specimen acceptable. Below we list some criteria for rejecting specimens.

- Inadequate specimen identification; for example, a specimen that is unlabeled or mislabeled.
- Inadequate volume of blood. This applies to anticoagulated specimens. A short draw dilutes the specimen and affects the results. For example, an EDTA short draw affects the packed cell value (PCV), cell count, and cell morphology.
- Specimen collected in wrong tube. Tubes are designed for specific testing purposes; for example, a clot tube drawn for complete blood count.
- Hemolysis. Hemolysis can affect several types of testing. Before discarding a hemolyzed specimen, consider the tests being ordered and the level of hemolysis.
- Improper transportation. This basically concerns specimens that require transport at body temperature or on ice; for example, cold agglutinins and semen analysis not transported and delivered at body temperature or blood gas specimens not on ice.

NOTE: *Never* discard a specimen before speaking with either nursing personnel or the physician. Following this discussion, make an annotation as to the determination on how to proceed with testing or specimen disposition for that particular specimen. Always initial your comments to provide an audit trail. Below we provide four examples with three like alpha characters trailing the comment to represent technician initials:

1. Inadequate specimen volume—unable to complete all tests as requested. XXX
2. Specimen improperly transported to lab; temp upon receipt was ##°C. YYY
3. Specimen not received in a timely manner. Spoke to Maj. Smith in the Internal Medicine Clinic, who instructed lab to perform all requested testing. Potassium results may not be valid because of delay in specimen transport to lab. ZZZ
4. Specimen grossly diluted. Contacted Capt. Jones on ward 2W who indicated that a new specimen will be collected and submitted. QQQ

Processing specimens within a central or sectional area

Processing specimens can be done in a central processing area or within each section; this information pertains to both areas. First, always check specimen identification with the request form or computer printout. If discrepancies arise, do nothing else with the specimen until the problem is resolved. If it cannot be resolved, a new specimen must be provided or collected. Second, check the specimen for

appropriate collection tube, transport temperature, and volume. If these criteria are met, the specimen can be separated and stored.

Separation

Separation is not required for all specimens (e.g., specimens for whole blood analyses). Plasma can usually be acquired immediately, because anticoagulated blood can be centrifuged right away. However, procedures that require serum take a little longer to process. Blood normally clots completely within 30 to 60 minutes at 22 to 25°C. This varies if the patient is on anticoagulant therapy, such as heparin or coumarin. Specimens should clot completely, but on the other hand, they should be centrifuged and separated as quickly as possible to avoid constituent changes. Red cells remain viable in vitro and absorb constituents from serum and plasma. This can cause falsely elevated or decreased results. Separate specimens within 2 hours of collection. If a specimen cannot be centrifuged within this time period, keep it at room temperature to decrease the amount of hemolysis. When centrifuging specimens, the stopper should remain on the tube to prevent infectious aerosols. After centrifugation, pour or pipette the serum or plasma into a clean, clearly labeled tube with a cap. The cap must fit tightly to reduce both the evaporation and concentration of certain constituents, which can result in erroneous test values.

Storage

After separation, specimens are refrigerated, frozen, or left at room temperature depending on procedural requirements. Familiarize yourself with the various procedures and storage requirements in your laboratory. If you aren't sure, check with the receiving section, the OI, or the laboratory guide.

Specimen appearance after separation

Often the appearance of the serum or plasma can alert you to possible procedural interference or incorrect results.

Hemolysis

Hemolysis is due to hemoglobin being released when red cells are lysed. The specimen takes on red color that varies depending on the severity. Hemolysis is usually a result of a traumatic venipuncture. It can also be caused by prolonged contact of serum and cells and by warming, freezing, or rough handling of the specimen. Hemolysis affects many blood constituents. Review test methodology for each procedure if hemolysis is a concern. You cannot use hemolyzed specimens for transfusion services or coagulation procedures.

Icteric specimens

Icteric specimens are yellowish or brownish in color and may be a result of jaundice. The color is due to bile pigments, mostly bilirubin, in the serum or plasma. Depending on the procedural principle and instrumentation, icteric specimens may or may not affect results. Again, review methodologies and procedural limitations.

Lipemic specimens

Milky-white specimens contain lipids or fats within the serum or plasma and are called lipemic. Lipemia is a result of drawing a specimen right after the consumption of a meal or from improper fasting. However, some patients may have an extremely large amount of lipids in their serum, even after fasting. If the specimen is severely lipemic, you can place it in an ultracentrifuge, if one is available. The ultracentrifuge separates the lipids from the serum or plasma. Lipemia can interfere with photometric measurements.

Shipping specimens to referral laboratories

As we stated earlier, it is impossible for a laboratory to perform all the testing procedures at a physician's disposal. Therefore, referral laboratories are used for different tests. The referral

laboratory establishes specimen requirements. Normally they require more specimen than is needed; this allows the referral laboratory enough specimen to do repeat testing if necessary. The use of referral laboratories requires the specimen to be shipped or transported to another facility. Shipping biological specimens is regulated by the state and other agencies. If you need to ship a specimen, your laboratory must follow these regulations. These regulations describe how to pack specimens, what type of packing material to use, use of interior and exterior shipping containers, and labeling or identification of the biological hazard. General instructions include those listed below:

- Ensure patient identification, test order, and all attached labels are accurate and clearly labeled.
- Avoid shipping specimens in glass containers.
- Wrap specimen in an absorbent material and place in a ziplock bag to prevent a safety hazard and contamination if it leaks.
- Pack specimens with enough ice or dry ice to last for 72 hours.
- The outer transport container should be constructed of strong corrugated cardboard or Styrofoam if the specimens need to be iced.
- Proper handling of specimens ensures quality results, which, in turn, provide quality patient care.

017. Medical terminology

As we stated earlier, like any other occupation or profession, members of the medical service use unique terms and expressions to communicate with one another. For you to effectively understand what other members of the health-care team are talking about, you need to know medical terminology. We discuss the elements of medical terminology and how these elements are combined to form medical terms. Before you can become an adept “medical linguist,” you need to learn more about the various components or elements that are combined to form medical words.

Elements of medical terminology

A great number of the words used in medicine are formed by combining units called *prefixes*, *suffixes*, and *root words*. Most medical words are derived from ancient Greek and Latin word components. We start by discussing word components that appear in the first part of a medical term—prefixes.

Identifying medical prefixes

Perhaps the best way to begin a lesson on terminology is to analyze the meaning of a prefix. A prefix is a syllable or group of syllables joined to the beginning of a root word to alter its meaning or create another word. Prefixes are always used in conjunction with a root word or with a root word and suffix; they cannot stand alone to form a word or term. With this definition fresh in your mind, carefully study the following list of medically related prefixes, accompanied by their definitions. The list is arranged in alphabetical order to facilitate learning.

Prefix	Definition	Prefix	Definition	Prefix	Definition
a-, an-	absence of	exo-, e-	outside	neo-	new
ab-, abs-	away, from	extra-	outside, beyond	non-	not
ad-	to, towards, near	fore-	in front of	olig-	little
aer-	air	glyco-	sugar	pan-	all
ambi-	both	hemi-	one half	para-	beside
ante-, antero-	before, forward	hetero-	other	peri-	around

Prefix	Definition	Prefix	Definition	Prefix	Definition
auto-	self	homo-	same, similar	poly-	many, much
bi-	two	hydra-, hydro-	water	post-	after
bio-	life	hyp-, hypo-	below, less	pre-	before
brady-	slow	hyper-	above, excessive, over	pro-	before, in front of
circum-	around	in-	not, in	pseud-, pseudo-	false
co-, com-, con-	with, together	infra-	below, beneath	retro-	backward, behind
contra-	against, opposed	inter-	between	semi-	half
de-	from, not	intra-	within	sub-	under
dia-	across, through, apart	iso-	equal	super-	above, excess
deca-	ten	latero-	side	supra-	over, above
demi-	half	leuco-, leuko-	white	sym-, syn-	with, together
di-	two	macro-	large	tachy-	fast
dis-	negative, apart	mal-	bad, disordered	topo-	place
dys-	difficult, painful	med-	middle	tox-	poison
ecto-	on the outside	meg-, mego-	great, large	therm-, thermo-	heat
en-	in	melan-	black	trans-	across, through
endo-	within	meno-	monthly	tri-	three
epi-	upon	meta-	beyond	ultra-	excess
erythro-	red	micro-	small	uni-	one
eu-	well, normal	mono-	single		
ex-, e-	away from, without	multi-	many		

There are many more prefixes we could add to this list, but the ones listed should give you a good foundation on which to build your medical vocabulary. Let's take a look at one of these prefixes and see how it is used to make a word. You are probably familiar with the word "biology," but did you ever stop to think where this word came from? Actually, biology is a combination of two Greek words: "bio," meaning "life," and "logy," meaning "the study of" or "the science of." When you combine "bio" and "logy," you form the word "biology," which means the science or study of life. Simple, isn't it? "Biology" is just one example of how a prefix is combined with other word components to form a term with a definite meaning. If you study (and memorize) the prefixes in the preceding list, you can break down just about any medical term and figure out what it means. Of course, to fully analyze medical terms and decipher their meaning, you also need to understand the elements of medical language that appear at the tail end of a word—suffixes.

Commonly used medical suffixes and their meanings

A suffix is a syllable or group of syllables added at the end of a word or word base to change its meaning, to give it grammatical function, or to form a new word. Suffixes may be found in combination with a prefix and a root word or just with a root word. Like prefixes, suffixes cannot be

used alone to form a word or term. As we did with prefixes, we look at a list of some common suffixes, along with their meanings, that are used to form medical terms.

Suffix	Meaning	Suffix	Meaning	Suffix	Meaning
-algia	pain	-graphy	making a recording	-pexy	fastening, fixation
-asis	condition, usually abnormal	-iasis	condition of	-phagia, -phagy	relating to eating and swallowing
-asthenia	weakness	-iatry	treatment of a disease	-phasia	ability to express one's self
-biotic	living matter	-ism	a condition	-phobia	exaggerated fear
-cele	tumor, cyst, hernia	-itis	inflammation	-plasty	surgical reshaping or remodeling
-centesis	puncture and aspiration of	-ize	to treat by a special method	-plegia	paralysis
-cide	causing death	-ilith	stone or calculus	-poiesis	formation of
-cyte	cell	-logy	science or study of	-ptosis	falling, sagging, or dropping down
-desis	binding or fusion	-lysis	destruction of, decomposition	-rhage, -rhagia	excessive flow, breaking/ bursting forth
-ectasis	dilation, stretching	-malacia	softness, softening	-rhaphy	a suturing or sewing
-ectomy	removal of	-megaly	enlargement	-rhea or -rrhea	flow, discharge
-emia	blood	-meter, -metry	measurement, measuring instrument	-scope	lighted examination instrument
-esthesia	feeling, sensation	-oid	form, shape, resemblance	-scopy	examination using a scope
-gene	production, origin	-oma	tumor	-stasis	a standing still
-genic	producing	-osis	process (usually disease)	-stomy	to create an opening
-gram	a tracing or mark	-pathy	disease, suffering	-tomy	incision or cutting into
-graph	a writing or record	-penia	lack or reduction in number of	-uria	relating to urine

Although limited, this list contains enough suffixes to strengthen your vocabulary. Now, look at how these suffixes are used to form a medical term. For our example this time, let's try something a bit harder than the one we used to illustrate prefix use. If the word "tracheo" refers to your trachea or throat area, how would you change the word to mean "a surgical incision into the trachea or throat"? If you look through the preceding list, you will see that the suffix "-tomy" (or "-otomy") means "incision or cutting into." To make the word you want, simply add one of these suffixes to the root word "tracheo." The term you formed by combining the two elements is "tracheotomy," which basically means a "surgical incision into the throat or trachea." You probably noticed that there is very little difference between the meanings of some of these suffixes but that there is a significant difference in the way they are spelled (and used). It is very important that you pay particular attention to learning the subtle differences so that you do not confuse and misinterpret a term. No discussion of medical terminology would be complete without mentioning the elements that form the "heart" of medical terms—root words.

Root words that relate to the human body and its processes

With the definitions of medical prefixes and suffixes fresh in mind, you now have the basis for becoming proficient in the language of your profession. However, to become more familiar with terms that apply to human anatomy and physiology, you need a knowledge of commonly used medical root words. A root word can be defined as “the main part or portion of a word from which other words may be formed by the addition of a prefix, a suffix, or both.”

NOTE: Very often, a vowel is added when two root words are combined or when a suffix is added to a root word. This *combining vowel* is usually an “o” or an “i,” but a “u” is sometimes used. This combining vowel is used to make pronunciation easier when there is no vowel between the two root words or between the root word and suffix.

The following alphabetical list of root words and their definitions relate to the human body and body processes. The most common combining vowel is shown in parentheses.

Root Word	Definition	Root Word	Definition	Root Word	Definition
abdomin(o)	abdomen	glyc(o)	sugar	pharyng(o)	pharynx
acou(i)	hearing	gyn, gyne, gynec(o)	woman	phleb(o)	vein
aden(o)	gland	hem, hema, hemo, hemat(o)	blood	physio	relating to nature, life
adren(o)	adrenal gland	hepat(o)	liver	pneum(o)	lung or air
angi(o)	vessel (usually blood vessel)	hydr(o)	water	proct(o)	rectum
arterio	artery	hyster(o)	uterus	psych(o)	mind, soul
arthr(o)	joint	ile(o), ili(o)	ileum	pulmo	lung
audi(o)	pertaining to hearing	jejuno(o)	jejunum	py(o)	pus
bil(i)	relating to bile	kerat(o)	cornea	pyel(o)	pelvis of the kidney
blephar(o)	relating to an eyelid or eyelash	kinesi(o)	movement	rect(o)	rectum
brach(i)	arm	laparo	abdomen, loin, or flank	ren(i)	kidney
bronch(o)	pertaining to a bronchus or the bronchi	laryng(o)	larynx	rhin(o)	nose
calcane(o)	heel	latero	side	sacro	sacrum (vertebra)
card(i), cardi(o)	pertaining to the heart	lip(o)	fat	salping(o)	tube (uterine or auditory)
carp(o)	wrist	lith(o)	stone	sarc(o)	flesh (skeletal muscle tissue)
cephal(o), capit	head	lymph	watery fluid from special gland	splen(o)	spleen
cervic(o)	neck	mamm(o)	breast, mammary gland	spondyl(o)	vertebrae, spine
chole, chol(o)	bile	mast(o)	breast,	sten(o)	narrow,

Root Word	Definition	Root Word	Definition	Root Word	Definition
			mastoid process		constriction
cholecyst	gallbladder	mening(o)	membrane	stern(o)	sternum
chondr(o)	cartilage	meno	menstruation	stomato	mouth
col(o)	colon (large intestine)	metra, metro	uterus	teno, tenonto	tendon
colpo	vagina	myel(o)	bone marrow, spinal cord	therm(o)	heat
cost(o)	rib	my(o)	muscle	thoraco	chest, thorax
crani(o)	skull	nas(o)	nose	thromb(o)	clot, thrombus
cyst(o)	urinary bladder, cyst	necro	death	thyr(o)	thyroid gland
cyt(o)	cell	nephr(o)	kidney	tox(o)	poison
dactyl(o)	finger or toe	neur(o)	nerve	toxic(o)	poison, poisonous
dent(o)	relating to a tooth or the teeth	ocul(o)	eye	trachel(o)	cervix
derma	skin	oophor(o)	ovary	trache(o)	trachea
doch(o)	duct	ophthalm(o)	eye	uretero	ureters
duoden(o)	duodenum	opto	relating to vision	urethro	urethra
encephal(o)	brain	orchi(o)	testicle	ur(o), urin(o)	relating to urine or urinary organs
enter(o)	intestines	orth(o)	straight, normal, correct	uter(o)	uterus
fibr(o)	fiber, fibrous	os	bone or opening	vas(o)	blood vessel, vas deferens
gastr(o)	stomach	oste(o)	bone	ven(o)	vein
genu	knee	ot(o)	ear	ventri, ventro	abdomen
gloss(o)	tongue	path(o)	relating to disease	vertebr(o)	spine, vertebrae
gluc(o)	glucose, sweetness	ped(o)	child, foot	vesico	urinary bladder

As was the case with the prefixes and suffixes that were previously listed, this list of root words is not all-inclusive. You probably noticed that many of these root words do not look or sound like the subjects they describe. The reason for this is that most of them are derived from ancient Greek and Latin, as are the other elements that you have studied. If you take the time to learn the elements of medical terminology presented in this lesson, you should be able to look at most medical terms and determine their meaning (or at least be fairly close). When you put all these word components together in different combinations, you formulate the words and expressions that are an integral part of everyday communication between members of the health-care team.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

016. Specimen processing

1. List the four questions you must ask yourself when you receive a specimen.
2. List five reasons for rejecting a specimen.
3. Why do you centrifuge specimens as quickly as possible?
4. Describe hemolysis and what is it a result of?
5. Describe icteric and what is it a result of?
6. Describe lipemic and what is it a result of?
7. Who decides specimen requirements for specimens sent to another laboratory?
8. How can you avoid a safety hazard or contamination when shipping a specimen?

017. Medical terminology

1. Define prefix.

2. Match the prefix in column B with the statement in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

<i>Column A</i>	<i>Column B</i>
____ (1) Little.	a. an.
____ (2) Absence of.	b. bio.
____ (3) Excess.	c. co.
	d. dys.
	e. erythro.
	f. glyco.
	g. intra.
	h. leuko.
	i. melan.
	j. olig.
	k. para.
	l. retro.
	m. super.
	n. supra.
	o. tachy.
	p. ultra.

3. Define suffix.

4. Match the suffix in column B with the statement in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

<i>Column A</i>	<i>Column B</i>
____ (1) Puncture and aspiration of.	a. -algia.
____ (2) Decomposition.	b. -centesis.
____ (3) Formation of.	c. -ectomy.
	d. -esthesia.
	e. -lysis.
	f. -megaly.
	g. -pexy.
	h. -plasty.
	i. -plegia.
	j. -poeisis.
	k. -rhagia.
	l. -rhaphy.
	m. -scopy.
	n. -stasis.
	o. -stomy.
	p. -tomy.

5. Define the term “root word.”
6. What is the purpose of a combining vowel?
7. Match the root word in column B with the statement in column A by placing the letter of the column B item beside the number of the column A item that most nearly describes it. Each item in column B may be used once, more than once, or not at all.

<i>Column A</i>	<i>Column B</i>
____ (1) Muscle.	a. acou(i).
____ (2) Bone.	b. bronch(o).
	c. cardi(o).
	d. chondr(o).
	e. colpo.
	f. cyt(o).
	g. dactyl(o).
	h. derma.
	i. enter(o).
	j. hemat(o).
	k. kerat(o).
	l. lith(o).
	m. my(o).
	n. oste(o).
	o. spondyl(o).
	p. trachel(o).
	q. ven(o).
	r. vesic(o).

4-3. Point-of-Care Testing

Point-of-care testing (POCT) has been around for a number of years. In the early 1980s the first whole blood glucose analyzers appeared in response to patients needs to home blood test for diabetic management. This was the first time that laboratory testing was actually taken *out* of the traditional laboratory setting and performed elsewhere and that laboratory testing was not being performed by trained laboratory personnel. This was the beginning of the evolution of POCT. Essentially POCT refers to laboratory testing that is performed outside of the laboratory setting, using generally simple to operate, portable, accurate, and reproducible devices. Other names for POCT include: alternate site testing, ancillary testing, bedside testing, decentralized testing, distributed testing, near-patient testing, patient focused testing, value-added testing, and waived testing.

018. Point-of-care testing

In this lesson, we take a look at the benefits and contraindications of having a POCT program in your MTF. We present a brief overview of the clinical regulatory considerations you must be aware of when using this type of laboratory testing. We also look at the structure of a POCT program and its administration. Finally, we discuss the training, procedures, and technology involved in POCT.

Benefits of POCT

The potential benefits of POCT are numerous. Most of the benefits for the providers, nurses, patients, and administration are based on the belief that “faster care is better care” and that the more rapid testing by POCT would improve medical care and decrease utilization of MTF resources. The MTF resources include (but are not limited to) supplies, bed space, and personnel. Other possible benefits of POCT include minimizing sample size because many of the testing methods use finger sticks rather than tubes of blood and increasing the patient’s sense of involvement in his or her own medical care. Some of the benefits gained by the MTF by having a POCT program are listed in the following table:

For the providers:	Improved therapeutic turnaround time. Better and more immediate care.
For the patients:	Patient-focused system. Less traumatic (for finger stick systems). Improved convenience. Less blood withdrawn.
For the laboratory:	Decreased preanalytical errors. Improved visibility. Decreased manpower needs. Collaboration with clinicians (providers). Direct patient involvement. Team management system.
For administration:	Shorter intensive care stays. Decreased overall length of hospital stays. Financial savings. Total quality management (TQM) program.

The most significant benefit of POCT is the immediate assessment and management of critically ill patients. Over 40 different analytes have been evaluated as potential POCTs. Based on the criteria of “immediate medical need,” we only consider blood gases, electrolytes (Na^+ , K^+ , Ca^{++}), prothrombin time (PT), partial thromboplastin time (PTT), hematocrit or hemoglobin, and glucose.

Contraindications of POCT

When either defining the benefits or contraindications for the use of POCT, the most important consideration to keep in mind is whether it is the most appropriate testing mechanism to be used in a particular setting. We must remember that POCT is only one way of providing test results for patients with critical needs. Rather than a POCT program, would the creation of a STAT or satellite laboratory better serve the needs of the patients in your MTF? These are decisions that we, as laboratory technicians, may not get directly involved in, but none the less, we need to be aware of. Probably, the most negative aspect of POCT is its cost. Generally, POCT analyzers have higher reagent costs and require more disposable items to perform testing than traditional laboratory analyzers.

Clinical regulatory considerations for POCT

POCT performed in all MTFs fall under the guidelines of numerous regulatory agencies and laws that govern laboratory procedures, regardless of where they are performed. The following is an overview of what all of us need to be aware of when our laboratories become a part of POCT programs.

CLIA '88

The Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) is the primary law regulating POCT. Implemented in 1992, CLIA affects all tests performed in any setting—inside or outside of the laboratory. CLIA describes the regulatory requirements and standards that must be met for every procedure used in the testing of human specimens to provide information for the diagnosis, treatment,

and evaluation of humans. In an individual laboratory, CLIA compliance requirements are based on the complexity of the testing they perform. The test complexity categories are based on the difficulty of each procedure performed and the training required to accurately perform each test. The categories are as follows:

- Waived tests—these procedures are classified as simple and only require a certificate from CLIA for their performance.
- Moderately complex tests—this category of testing is classified as more difficult by CLIA, requiring proficiency testing and more technically trained personnel to perform them.
- Highly complex tests—are classified by CLIA as most difficult to perform, requiring extensive quality assurance, proficiency testing, and performance by laboratory personnel to maintain a testing certificate.

Waived tests

Under CLIA, waived testing requires the laboratory to register the procedure and follow the manufacturer's directions to obtain a waived certificate. However, waived tests are not subject to proficiency testing, and they do not require highly skilled (trained) personnel to perform. They also don't require extensive quality control, comprehensive record keeping, and government inspections. Examples of waived testing are urinary reagent strip tests and the microhematocrit. The home glucose devices that have been cleared by the Food and Drug Administration (FDA), such as the OneTouch, Glucometer, and Accu-Chek, are considered waived by CLIA.

Moderately complex tests

This category of testing requires more highly trained personnel, a procedure manual, instrument calibration instructions, specific quality control, proficiency testing, and extensive documentation and record keeping. Unlike waived tests, these tests involve many steps to perform and are more likely to produce incorrect results if personnel are not properly trained to perform them. Most POCT procedures fall within the waived or moderately complex categories. All POCT instruments, other than the home-use devices for glucose, are probably categorized as "moderately complex methods." In fact, a new subcategory within CLIA is being considered called "accurate and precise technology (APT) tests." This new category would include most of the POCT methodologies because they must be easy to use, accurate, reproducible, and automated, and the results must be provided by direct readout. The manufacturer must provide complete instructions on QC, a step-by-step procedure, specimen collection methods, and sources of error, specimen requirements, normal ranges, and panic values. Plus, the manufacturer must be able to demonstrate that nonlaboratory personnel can perform the testing accurately and precisely.

Joint Commission on Accreditation of Healthcare Organizations

As we know, in 1986 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) developed a strategic plan for improving health care. The scope of their strategic plan was to improve both the quality of health care and customer satisfaction. Although waived tests under CLIA have had minimal requirements for compliance for things such as quality control, training of personnel, and documentation, JCAHO requires QC every day on automated instruments, documentation of any corrective action taken, and competency documentation of testing personnel. The requirements for moderately complex analysis, the other CLIA category POCT encompasses, are extensive. This is something good to keep in mind when setting up or modifying your current POCT program—what might keep you in compliance with one regulatory organization may not for another. We need to know the rules!

College of American Pathologists

The College of American Pathologists (CAP) checklist for POCT, dated September 2001, gives POCT the following definition:

POCT refers to those analytical patient testing activities provided within the institution, but performed outside of the physical facilities of the clinical laboratories. The central criterion of POCT is that it does not require permanent dedicated space. Examples include kits and instruments that are hand-carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g., capillary blood glucose), or analytic instruments that are temporarily brought to a patient care location (e.g., operating room, intensive care unit).

Also, CAP does not subclassify the tests being performed according to the federal (CLIA '88) system of “waived,” “moderate complexity,” “high complexity,” and “provider performed microscopy.” All CAP standards are considered “site neutral,” meaning to us that *all* tests must be correctly performed for patient care. The CAP standards for POCT supply guidance and requirements to our laboratories in these areas: proficiency testing, quality control (quality improvement, procedural manual, specimen handling, reporting results, reagents, calibration and standards, controls, instrument and equipment, personnel), personnel, and laboratory safety. As you can see, CAP standards cover all of the important areas of concern that also cover testing within the clinical laboratory. Their goal is to ensure that POCT is just as valid and accurate as the testing performed on the “big” analyzers in the laboratory.

Commission on Office Laboratory Accreditation

The Commission on Office Laboratory Accreditation (COLA) regulates physicians’ office laboratories. Under COLA, records for waived tests are not inspected; however, with moderately complex procedures, QC, method evaluation, and equipment validation are fairly extensive. COLA regulates any laboratory procedure performed in a physician’s office. As we know, most health-care providers can be trained to competently perform POCT analyses. However, because most POCT procedures are classified as “moderately complex” and because of the variety of agencies and regulations that oversee POCT, regulatory compliance requires the expertise of a registered clinical laboratory scientist to perform the testing.

NCCLS standards

The National Committee for Clinical Laboratory Standards develops standards based on voluntary consensus of current practices in all areas of laboratory science. Two of NCCLS’s documents that would be helpful to have in your laboratory to establish principles and practices for all POCT procedures are listed below:

1. AST2–A, *Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline* (1999): this publication contains guidelines for the users of IVD devices outside of the clinical laboratory to produce reliable results comparable to those obtained in the clinical laboratory.
2. C30–A2, *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guidelines – 2d Ed.* (2002): this document provides guidance for performing point-of-care blood glucose tests, with an emphasis on QC, training, and administrative responsibilities.

We refer to other NCCLS documents later.

NOTE: When working in your laboratory, always make sure you are referencing the most current edition of the required NCCLS document.

POCT policies and accountability

For all aspects of your POCT program, your organization must develop written policies addressing the roles of authority, responsibility, and accountability.

Authority

The individual (or group) within your MTF with *authority* is ultimately responsible for making and enforcing the policies that ensure quality test results. According to NCCLS, this individual should be designated with the authority to do the following:

- Make and enforce policy.
- Assign responsibility.
- Address problems.
- Make decisions about the program's structure.
- Provide administrative support.
- Provide quality oversight.

In a hospital-based POCT program, this person is likely to be the pathologist or the laboratory director (officer) who fulfills CLIA requirements. The responsibility for the management of a non-hospital-based POCT program, according to NCCLS, should be through the affiliation with a pathologist or laboratory director of a parent health-care organization or through a clinical consultant with the proper credentials. In the Air Force, it is possible to be assigned to either type of facility.

Because of the unique nature of POCT—having nonlaboratory personnel performing laboratory tests—decisions about the functions and processes, policies, and decisions are often made in a committee setting. These interdisciplinary POCT committees set the pace for the team approach required for the program to work efficiently. The makeup of the committee should represent all disciplines within your MTF involved in the POCT program, such as medicine, nursing, laboratory, respiratory therapy, and administration. The laboratory director or a designee chairs the committee.

Responsibility

One or several members of the laboratory staff are *responsible* for the evaluation of instruments and test kits, the training of personnel performing the testing, and developing the POCT procedural manual. The people assigned to the duty must be registered laboratory medical technologists or clinical laboratory scientists. They must be skilled in the validation of test procedures and instrumentation and in the statistical evaluation of QC data. Other duties they perform include developing a QA program, evaluating QC data, maintaining the program's compliance with regulatory agencies, and developing a working relationship with physicians, nursing staff, or other individuals involved in POCT.

Accountability

The actual individuals performing the testing, whether they are members of the laboratory staff or not, are ultimately *accountable* for the following: (1) understanding the principles and limitations of the procedures they perform, (2) performing and documenting QC and maintenance, as appropriate, (3) maintaining proficiency in testing methods, (4) performing and documenting test results according to procedure, and (5) following protocols for remedial actions or notification of responsible personnel. Having a thorough POCT training program and well-written procedural manuals makes this job a lot easier for all involved.

Training

As we know, laboratory personnel don't generally perform the actual POCT. Nurses, anesthesiologists, physician assistants, and medical technicians (4N0X1s) are among those who may be involved in the collection of samples and the performance of the tests. Qualifications for personnel performing POCT are set, as a minimum, by the state, local, and federal requirements. The laboratory director, who is responsible for the POCT program, has the right to set additional training requirements as that individual sees fit. The minimum education and experience requirements for individuals performing POCT can range from a high school diploma with no experience to a college

degree with laboratory experience. The amount of training time required to allow an individual to perform POCT depends on both the background of that individual and on the analytical system (machine or test kit) being used. All POCT training programs must include the following information for the learner:

- The theory of instrument/device being used.
- Specimen collection.
- Instrument maintenance requirements, if applicable.
- Quality control procedures.
- Testing procedures.
- Sources and degree of preanalytical errors.
- Clinical significance of results.

The greatest source of error in POCT, as well as laboratory testing in general, is preanalytical errors. As we know, preanalytical errors are factors that alter the results of laboratory tests and that occur before the actual performance of the testing. For more information on preanalytical errors, refer to the quality assurance lesson in this CDC volume. Because of the variety of personnel performing the testing, we suggest that the POCT training program include pretraining and posttraining written tests and practical tests that demonstrate acceptable performance for collecting patient specimens and for performing the analysis. Plus, all individuals must be required to annually recertify their competencies by written and performance testing. For additional guidance on POCT training programs, refer to NCCLS document GP21-A, *Training Verification for Laboratory Personnel; Approved Guideline*.

Procedures

We in the clinical laboratory are very accustomed to following the step-by-step instructions of an OI to perform our jobs. As we know, in the clinical laboratory, OIs have a set format to meet regulatory requirements. POCT lives under the same rules. You must have written procedures, in the form of a procedural manual, for each testing device and method used in your POCT program. NCCLS document GP2-A4, *Clinical Laboratory Technical Procedure Manuals; Approved Guideline*, suggests that the following areas be addressed for each procedure:

- Principles of operation.
- Purpose of the test.
- Specimen collection and handling.
- Preparation of reagents and other materials.
- Calibration and calibration verification.
- Quality control procedures.
- Stepwise instructions.
- Reporting results.
- Reporting of medical alert (panic) values.
- Limitations of procedure.
- Updates.
- Literature references.
- Remedial actions when out-of-control.
- Reference intervals (“normal values”).
- Specimen storage, stability, and preservation (if applicable).
- Action if test system inoperable.

- Criteria for referral of specimens.
- Infection control and safety.

This seems like a lot of information to cover, but remember, generally POCT is performed by nonlaboratory personnel, people who are not accustomed to following highly technical laboratory OIs. The intent of the POCT procedural manuals is to provide the basic foundation of knowledge to competently train nonlaboratory health-care workers to understand *any* new POCT procedure and to accurately perform it on *any* POCT instrument. We in the laboratory will probably be involved in the writing and updating of the POCT procedural manuals. If we follow the guidance given to us from NCCLS and remember who the users of the manuals will be, we should be able to produce a product that ensures the best results for our POCT program.

Quality assurance

As laboratory technicians, we have been taught that quality control is traditionally accomplished by “running” multiple levels of QC materials within each *analytical run*. Then, after applying various statistical rules (for example, 2SD or Westgard) to the results, we determine if the run is “in control” and if we can use the patient results. As defined by NCCLS and incorporated into the CLIA ’88 regulations, an analytical run for the purpose of QC is “an interval (that is, a period of time or series of measurements) within which the accuracy and precision of the measuring system are expected to be stable.” Maximum run length has been set for 24 hours. The concept of run length does not exist with most POCT single-use diagnostic testing analyzers, where, strictly speaking, each test run is a run unto itself. For example, with instrument-based test systems, every time a new cartridge pack or test strip is inserted into the base instrument, a new test system is created. Therefore, with POCT QC and, for that matter, all levels of QA take on a whole new dimension compared to what we are used to within the walls of the clinical laboratory. We must take great care to follow the manufacturer’s QC and calibration directions and to be aware of all QA POCT regulatory guidance in order for us to produce the best POCT results possible.

POCT technology

The environment in which we perform POCT is very unlike that of a traditional laboratory because of the different workflow and workload characteristics. Plus, generally the personnel working with POCT testing are more oriented to obtaining results quickly for their immediate use for patient care and are not, like laboratory technicians, necessarily committed to all the procedures associated to laboratory testing, such as QC, analytical procedures, accurate record keeping, and regulatory requirements. Consequently, to ensure the best possible results, the “ideal” characteristics of any POCT system would include the following:

- Is self-contained and portable.
- Has a flexible test menu.
- Requires minimal training; is simple to operate.
- Uses small volumes of whole blood.
- Has an accuracy and precision comparable to main laboratory systems.
- Performs automatic and periodic calibrations.
- Requires minimal routine and preventive maintenance.
- Has bar codes for test packs, controls, and bar-code reader for specimens.
- Reagents are stable at ambient temperature storage.
- Generates results printouts.
- Can be interfaced with the laboratory information system.
- Provides QA software, system lockouts, and data management.

As we can see, the “ideal” characteristics of a POCT system are similar to but very distinct from what we are used to in the clinical laboratory. Significant differences of the POCT systems to ours mainly involve the desire for the POCT system to be easy and convenient to use; that is, involving no venipuncture or precise pipetting, having procedural techniques that are simple and easy to follow, and having automated record keeping that fulfills regulatory requirements. POCT systems are grouped into two major categories; we define them as *non-instrument-based systems* or *instrument-based systems*.

Non-instrument-based systems

The most common forms of POCT are the non-instrument-based systems that utilize competitive and noncompetitive immunoassay, enzymatic assays, or chemical reactions with visually read end-point. We can analyze a variety of specimen types, such as whole blood, serum or plasma, urine, amniotic fluid, saliva, and feces, with these types of systems. Qualitative assays with a visually read positive or negative indicator are the predominant form of this type of system. Systems based on competitive or noncompetitive immunoassays are used for detecting a variety of analytes including hCG, drugs of abuse, fetal lung maturity, cardiac markers, and markers for infectious diseases. Other major qualitative assays are occult fecal blood testing and the visually read blood glucose reagent strips. The glucose concentration can then be semiquantified by visual comparison of the color development on the glucose reagent strip to a color chart. Urine reagent strips systems are also semiquantitative and use both chemical and enzymatic reactions. These are but a few examples of non-instrument-based POCT systems.

Instrument-based systems

As the popularity of POCT has increased, instrument-based POCT systems have become very sophisticated. They have become highly automated, using only small amounts of sample, requiring minimal routine and preventative maintenance, and eliminating or automating calibration functions. These improvements in the functionality of POCT instruments have been aided by many factors, such as (1) advances in reagent stabilization; (2) the development and miniaturization of electrodes and biosensors; (3) the ability by manufacturers to produce relatively inexpensive, precise, disposable devices; and (4) the development of microcomputers and microelectronics. Putting all of these improvements together and continuing to refine what we have will only bring us closer to having the “ideal” POCT system, like that we defined a few paragraphs earlier.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

018. Point-of-care testing

1. Most of the benefits of a POCT program are based on what belief?
2. List the benefits a POCT program brings to the laboratory.
3. What is probably the most negative aspect of POCT?
4. What is the CLIA definition of waived tests?

5. How does CLIA define moderately complex tests?
6. What is the name of the new CLIA subcategory being considered?
7. What was the scope of the strategic plan of the JCAHO?
8. According to CAP, what is the central criterion of POCT?
9. What does COLA regulate?
10. What three roles must written policies developed for your POCT program address?
11. According to NCCLS, the individual (or group) within your MTF with authority over your POCT program should be designated to do what things?
12. Who is likely to have authority over a hospital-based POCT program?
13. What aspects of the POCT program does the person(s) with responsibility oversee?
14. Who are the individuals with accountability in your POCT program, and what are they accountable for?
15. What information must all POCT training programs include?
16. What is the greatest source of error in POCT testing? Is this also true of general laboratory testing?
17. What is the intent of the POCT procedural manual?

18. When it comes to QA and POCT, what can we do to make sure we produce the best results possible?
19. Into what two major categories are POCT systems grouped?
20. List the factors that have aided in the improvements in functionality of POCT instruments.

Answers to Self-Test Questions

013

1. The order or request for the laboratory to perform a procedure or blood test; by the health-care provider or another qualified individual.
2. This information includes patient's name, SSN or hospital ID number, and date of birth; physician's name; test ordered; date received; billing code; and room and bed number if an inpatient.
3. The instructions you give to your patient must be direct, fully explained, and professional.
4. Supplies include gloves, antiseptic (alcohol pads), sterile gauze, bandages, slides, and needle or sharps disposal container. The equipment required is a tourniquet, needle, syringe or evacuated tube system, and various evacuated tubes with or without anticoagulants.
5. The diameter of the interior shaft of the needle; smaller gauges are larger needles and higher gauges are smaller needles.
6. Condition and size of veins and chance for hemolysis.
7. Patients with small, fragile, poor, or difficult veins.
8. 18 gauge.
9. A butterfly or winged infusion set is excellent for collecting blood from infants, children, and elderly patients with fragile or difficult veins.
10. Because some procedures demand whole blood or plasma, the blood must be mixed with an anticoagulant in order to prevent clotting.
- 11.

Color	Anticoagulant	Section	Determination
Brown	Sodium heparin	Chemistry, Shipping	Lead levels
Dark Blue	Sodium heparin	Chemistry, Hematology, Special Chemistry, Shipping	Trace elements, toxicology, and nutrient determinations
Gray	Sodium fluoride	Chemistry, Special Chemistry, or Shipping	Glucose tolerance test
Green	Ammonium, lithium, or sodium heparin	Chemistry, Hematology, Special Chemistry, Shipping	Chemical analyses
Lavender	Liquid K ₃ EDTA, Freeze-dried Na ₂ EDTA	Hematology	Complete blood counts, differentials, and ESR
Light Blue	Sodium citrate	Coagulation	PT, PTT, and other coagulation studies
Red	No anticoagulant	Blood Bank	Blood typing, cross-matches, antibody and antigen studies

Color	Anticoagulant	Section	Determination
Red combination "Tiger-top"	Clot activators or gel	Chemistry, Immunology, Special Chemistry, Shipping	Antibody and antigen studies, chemical analyses
Yellow – Large tubes	Sodium polyanetholsulfonate (SPS)	Microbiology	Blood cultures
Yellow – Small tubes	Acid Citrate Dextrose	Immunology, Shipping	HLA tissue typing

12. This prevents cross contamination of anticoagulants or tubes containing media; blood culture, clot, citrate, heparin, EDTA, oxalate, and then fluoride tubes.

014

1. By comparing the request form with the information on the patient's identification or armband; if the patient is unconscious or comatose and there is no identification band, have a nurse identify the patient.
2. Check the patient's ID card, ask him or her to state name and SSN, or have him or her visually verify the information on the request form; don't ask yes or no questions.
3. 3 to 4 inches above the intended venipuncture site.
4. The median cubital vein is the preferred site because it is close to the skin surface. It is large and is surrounded by tissue that anchors it—preventing the vein from rolling (moving away).
5. Only if you consult a nurse or physician first; circulatory problems in lower extremities, diabetes in poor control, hemoglobinopathies, and edema.
6. One minute; areas with hematomas, edema, burns, or scars; and the arm on the side of a mastectomy.
7. (1) Drawing blood for alcohol determinations.
(2) Bacterial cultures.
(3) Blood donation.
8. Hooks, obstructions, or other defects.
9. Bending the arm can cause the wound to reopen, which may result in blood leaking into surrounding tissue.
10. Label the blood sample tubes with the patient's first and last names, ID number or SSN, the date and time of collection, and your initials.
11. The use of a 3 ml or tuberculin syringe with a 21- or 23-gauge needle.
12. Anchor the vein both above and below the venipuncture site; the elderly often have detached and floating veins.
13. Remove the tourniquet and needle immediately; carefully lower the patient to the floor, loosen tight clothing, administer an ammonia inhalant, and once the patient regains consciousness, apply cold compresses to his or her forehead and the back of the neck if necessary.

015

1. Puncturing deep veins in children this young can cause cardiac arrest, venous hemorrhage, venous thrombosis, reflex arteriospasm, gangrene of an extremity, damage to surrounding tissues, or infection. Also, the infant may be injured while being restrained for the procedure.
2. Infants, young and older children, young adults, adults, and the elderly; severely burned patients, extremely obese patients, geriatric patients, and patients who don't have usable veins.
3. Skin puncture supplies and equipment include gloves, sterile gauze, heel warmer or warm, moist towel, alcohol pads, bandages, capillary tubes, capillary tube sealant, microcollection tubes, volume pipettes for the Unopette system, glass slides, and possibly filter paper (PKUs) or reagent strips (glucose).
4. Approximately 50 to 75 µl of blood; a red band at one end of the tube indicates an ammonium heparin-coated tube, and a blue band indicates a plain tube.
5. Approximately 250 µl of blood and the tube is tapered at one end. A yellow band at the nontapered end indicates a lithium heparin-coated tube and nonanticoagulated tubes also have a blue band.

6. A site on the edge of the heel.
7. The end point can be as close as 2.4 mm from the bone and the arch has a lot of nerves, tendons, and cartilage.
8. In older children and adults, the fleshy surface of the distal phalanx (last joint) of the index, middle, or ring finger or thumb can be used.
9. It may contain tissue fluid.
10. Gently tap the tube on a hard surface.

016

1. (1) Has the proper container been used?
(2) Has the specimen been refrigerated?
(3) If it was frozen, has it thawed?
(4) Has the proper transmittal paperwork accompanied the specimen?
2. (1) Inadequate specimen identification.
(2) Inadequate volume of blood.
(3) Specimen collected in wrong tube.
(4) Hemolysis.
(5) Improper transportation.
3. To avoid constituent changes; red cells still remain viable and absorb constituents from serum and plasma.
4. Red color that varies depending on the severity; caused by hemoglobin being released when red cells are lysed.
5. Yellowish or brownish in color; due to bile pigments, mostly bilirubin, in the serum or plasma.
6. Milky-white specimens; due to lipids or fats in the serum or plasma.
7. The referral laboratory.
8. Wrap the specimen in absorbent material and place in a ziplock bag to prevent a safety hazard and contamination if it leaks.

017

1. A syllable or group of syllables joined to the beginning of another word to alter its meaning or to create another word.
2. (1) j.
(2) a.
(3) n, p.
3. A syllable or group of syllables added at the end of a word or word's base to change its meaning, give it grammatical function, or form a new word.
4. (1) b.
(2) e.
(3) j.
5. The main part or portion of a word from which other words may be formed by addition of a prefix and/or suffix.
6. A combining vowel is used to make pronunciation easier when there is nothing between the two root words or between the root word and the suffix.
7. (1) m.
(2) n.

018

1. That "faster care is better care" and that the more rapid testing by POCT would improve medical care and decrease utilization of MTF resources.
2. (1) Decreased preanalytical errors.

- (2) Improved visibility.
- (3) Decreased manpower needs.
- (4) Collaboration with clinicians (providers).
- (5) Direct patient involvement.
- (6) Team management system.
3. The cost.
4. These procedures are classified as simple and only require a certificate from CLIA for their performance.
5. This category of testing is classified as more difficult by CLIA, requiring proficiency testing and more technically trained personnel to perform them.
6. Accurate and precise technology (APT).
7. To improve both the quality of health care and customer satisfaction.
8. That it does not require permanent dedication space.
9. Physicians' office laboratories; they regulate any laboratory procedure performed in a physician's office.
10. Authority, responsibility, and accountability.
11.
 - (1) Make and enforce policy.
 - (2) Assign responsibility.
 - (3) Address problems.
 - (4) Make decisions about the program's structure.
 - (5) Provide administrative support.
 - (6) Provide quality oversight.
12. Either a pathologist or the laboratory director (officer) who fulfills CLIA requirements.
13. They will be responsible for the evaluation of the instruments and test kits, the training of personnel performing the testing, and developing the procedural manual.
14. The individuals actually performing the testing; they are accountable for the following:
 - (1) Understanding the principles and limitations of the procedures they perform.
 - (2) Performing and documenting QC and maintenance, as appropriate.
 - (3) Maintaining proficiency in testing methods.
 - (4) Performing and documenting test results according to procedures.
 - (5) Following protocols for remedial actions or notification of responsible personnel.
15.
 - (1) The theory of the instrument/device being used.
 - (2) Specimen collection.
 - (3) Instrument maintenance requirements, if applicable.
 - (4) Quality control procedures.
 - (5) Testing procedures.
 - (6) Sources and degree of preanalytical errors.
 - (7) Clinical significance of results.
16. Preanalytical. Yes.
17. To provide the basic foundation of knowledge to competently train nonlaboratory health-care workers to understand *any* new POCT procedure and to accurately perform it on *any* POCT instrument.
18. Take great care to follow the manufacturers' QC and calibration directions and be aware of all QA POCT regulatory guidance.
19. Non-instrument-based systems and instrument-based systems.
20. The factors are as follows
 - (1) Advances in reagent stabilization.
 - (2) The development and miniaturization of electrodes and biosensors.
 - (3) The ability by manufacturers to produce relatively inexpensive, precise, disposable devices.

- (4) The development of microcomputers and microelectrodes.

Do the unit review exercises before going to the next unit.

Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter.

25. (013) We use syringe systems for patients with
- good veins because you can control vacuum pressure, thus avoiding icteric specimens.
 - good veins because you can control vacuum pressure, thus avoiding collapsed veins.
 - fragile or difficult veins because you can control vacuum pressure, thus avoiding icteric specimens.
 - fragile or difficult veins because you can control vacuum pressure, thus avoiding collapsed veins.
26. (013) Which of the following is the correct tube collection order for drawing blood?
- Blood cultures, clot tubes, citrate, heparin, EDTA, oxalate, and then fluoride tubes.
 - Citrate, heparin, EDTA, oxalate, fluoride tubes, clot tubes, and then blood cultures.
 - Heparin, EDTA, oxalate, citrate, fluoride tubes, blood cultures, and then clot tubes.
 - EDTA, oxalate, fluoride, citrate, heparin, tubes, clot tubes, and then blood cultures.
27. (014) Which of the following is *not* a risk for parenteral administration?
- Nerve damage.
 - Tissue necrosis.
 - Infection or abscess.
 - Medication is totally absorbed.
28. (014) Why is the median cubital vein the preferred site for venipuncture?
- It is deep in the skin, it is large, and it is away from the tissue.
 - It is deep in the skin, it is small, and it is anchored by surrounding tissue.
 - It is close to the skin's surface, it is small, and it is away from the tissue.
 - It is close to the skin's surface, it is large, and it is anchored by surrounding tissue.
29. (014) When should you label the blood specimens or tubes?
- After leaving the bedside or side of the patient.
 - Before leaving the bedside or side of the patient.
 - After you take the specimen to the appropriate section.
 - Before you take the specimen to the appropriate section.
30. (014) When drawing blood from an elderly patient,
- big, hard veins can cause difficulty; anchor the vein below the venipuncture site.
 - big, hard veins can cause difficulty; anchor the vein both above and below the venipuncture site.
 - detached and floating veins can cause difficulty; anchor the vein above the venipuncture site.
 - detached and floating veins can cause difficulty; anchor the vein both above and below the venipuncture site.
31. (015) Microhematocrit or capillary tubes hold approximately
- 50 to 75 μ l of blood, with a blue band that indicates a plain tube.
 - 50 to 75 μ l of blood, with a red band that indicates a plain tube.
 - 250 μ l of blood, with a blue band that indicates a plain tube.
 - 250 μ l of blood, with a red band that indicates a plain tube.

32. (015) Caraway or Natelson tubes hold approximately
- a. 50 to 75 μ l of blood, with a blue band that indicates a lithium heparin-coated tube.
 - b. 50 to 75 μ l of blood, with a yellow band that indicates a lithium heparin-coated tube.
 - c. 250 μ l of blood, with a blue band that indicates a lithium heparin-coated tube.
 - d. 250 μ l of blood, with a yellow band that indicates a lithium heparin-coated tube.
33. (015) Which finger of an infant do you *not* use for skin puncture, and why?
- a. Index; the skin is too thin.
 - b. Pinkie; the skin is too thin.
 - c. Ring; the skin is too thick.
 - d. Middle; the skin is too thick.
34. (015) When performing a skin puncture, collect
- a. free-flowing blood and mix anticoagulated tubes 4 to 6 times.
 - b. free-flowing blood and mix anticoagulated tubes 8 to 10 times.
 - c. slow-flowing blood and mix anticoagulated tubes 4 to 6 times.
 - d. slow-flowing blood and mix anticoagulated tubes 8 to 10 times.
35. (016) Which of the following is *not* a criterion for specimen rejection?
- a. Proper transportation.
 - b. Inadequate volume of blood.
 - c. Specimen collected in wrong tube.
 - d. Inadequate specimen identification.
36. (016) Blood normally clots completely within
- a. 15 to 25 minutes at 2 to 8°C.
 - b. 15 to 25 minutes at 22 to 25°C.
 - c. 30 to 60 minutes at 2 to 8°C.
 - d. 30 to 60 minutes at 22 to 25°C.
37. (016) Specimens should be separated within
- a. 2 hours of collection.
 - b. 3 hours of collection.
 - c. 4 hours of collection.
 - d. 5 hours of collection.
38. (016) Who establishes specimen requirements for specimens that are shipped out to another lab?
- a. Physician.
 - b. Sending laboratory.
 - c. Referral laboratory.
 - d. Requesting laboratory.
39. (017) *Most* medical words are derived from
- a. ancient Greek and Latin word components.
 - b. modern Greek and Latin word components.
 - c. ancient Hebrew and Latin word components.
 - d. modern Hebrew and Latin word components.

40. (017) Prefixes are *always* used
- a. by themselves or with a suffix; they can stand alone to form a word or term.
 - b. by themselves or with a suffix; they cannot stand alone to form a word or term.
 - c. in conjunction with a root word or with a root word and suffix; they can stand alone to form a word or term.
 - d. in conjunction with a root word or with a root word and suffix; they cannot stand alone to form a word or term.
41. (017) Suffixes may be found in combination with
- a. a prefix and a root word or just with a root word; suffixes can be used alone to form a word or term.
 - b. a prefix and a root word or just with a root word; suffixes cannot be used alone to form a word or term.
 - c. another suffix and a root word or just with a root word; suffixes can be used alone to form a word or term.
 - d. another suffix and a root word or just with a root word; suffixes cannot be used alone to form a word or term.
42. (018) Which phrase describes a benefit of POCT to the laboratory?
- a. Improved convenience.
 - b. Decreased manpower needs.
 - c. Better and more immediate care.
 - d. Decreased overall length of hospital stays.
43. (018) The NCCLS develops standards based on
- a. voluntary consensus of current practices in all areas of laboratory science.
 - b. involuntary consensus of current practices in all areas of laboratory science.
 - c. voluntary consensus of current practices in limited areas of laboratory science.
 - d. involuntary consensus of current practices in limited areas of laboratory science.
44. (018) The amount of training time required to allow an individual to perform POCT depends on the
- a. size of the MTF.
 - b. training methods used.
 - c. time available for training.
 - d. background of the individual.

Please read the unit menu for unit 5 and continue. ➔

Student Notes

Unit 5. Clinical Chemistry Theory

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CHEMISTRY is the science dealing with the composition of matter and the changes in composition which matter may undergo. While chemistry is a tremendously large subject and is divided into many specialized fields, we only look at those with a direct connection to the clinical laboratory setting. As a laboratory technician, it is your task to analyze the various chemical constituents in blood, urine, and other body fluids or tissues. To produce the highest quality results, you need to understand how these various chemicals interact within the body and in the equipment you use to measure these analytes. Applying the chemistry principles you are about to learn will help you achieve your maximum potential as a laboratory technician and ensure the best in patient care.

5–1. Review of Chemistry Principles

By now, you have been exposed to some of the basics of chemistry through your Phase I and Phase II resident courses. Much of the information you will learn here is not necessarily new; rather, it builds further on what you have already studied. Let's review some of the basic terms and principles so that you start off with a rock-solid foundation.

019. Terms relating to atomic theory

Chemistry and atomic theories directly contribute to many of today's scientific breakthroughs. Radioactive elements have been incorporated into methods that aid in the diagnosis and treatment of diseases. The wide spectrum of medications available to patients today can alter the biochemical reactions that take place in the body. The further we progress, the more we learn about the atom and how big a part it plays in our lives.

Atoms

As you recall, the atom is the building block of all elements. An atom is the smallest component of an element that retains the characteristics of that element. Atoms are the smallest particle of an element capable of taking part in a chemical change.

Components of the atom

Atoms are comprised of three different particles. These particles we also sometimes refer to as subatomic particles. The nuclei (nucleus) of all atoms (except the lightest isotope of hydrogen, which only contains a proton and lacks neutrons) contain *neutrons* and *protons*. Orbiting the nucleus is the particle known as an *electron*. Let's briefly review these structures of the atom (fig. 5–1).

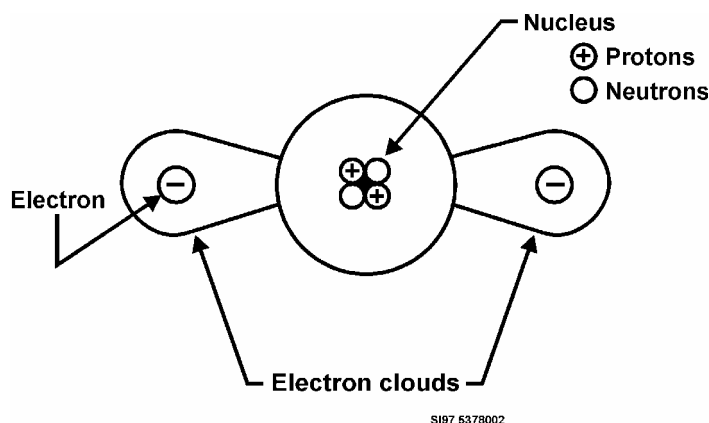


Figure 5-1. Atom structure.

Protons

A proton (p) is a particle with a positive charge of one (+1) and a mass of one atomic mass unit (AMU). When expressed as a number, the AMU is extremely small. The mass of a proton is 1.673×10^{-24} grams. Please note that when dealing with isotopes, we annotate the number of the isotope as a superscript; that is, raised and to the left of the element symbol. An example is the carbon-12 isotope (^{12}C). All atoms and isotopes of an element have the same number of protons in their nucleus. The number of protons in an atom directly corresponds to that element's atomic number. The periodic table of elements in appendix A provides atomic numbers for all elements.

Neutrons

A neutron (n) has the same mass as a proton (one AMU), but it does not have an electrical charge (neutral). The neutrons are believed to account for the degree of stability an atom's nucleus has. Atoms of the same element may have varying numbers of neutrons in their nucleus; these we call *isotopes* and we discuss them later. Remember, however, that the number of protons for any element remains constant.

Electrons

An electron (e) is a particle with a negative charge of one (-1) that orbits the atom's nucleus. It has a negligible mass, and for this reason, scientists ignore the electron's weight when determining an atom's total weight. Electrons circle the nucleus of an atom in spherical (three-dimensional) clouds called *orbitals*. We identify orbitals by designated numbers and letters. The energy level of the orbital determines the distance of an orbital from the atom's nucleus. If the orbital has a lower energy level, it will be closer to the nucleus; and if it is higher, then it will be further away from the nucleus. There are seven principal levels (designated by the letter "n" and the number of the energy level it represents) that we call *electron shells* or *energy levels*. Electrons and the energy shells they occupy are responsible for determining how an atom will react during a chemical change we refer to as bonding. We explore bonding later.

Electron shells

The electrons of an atom are arranged in a definite pattern within the various energy levels of the shells, and each shell is spaced at a given distance from the nucleus. To illustrate, think about an onion. As you peel an onion, each layer is a specific distance from the center. If you continue to peel away each layer, eventually you reach the center or nucleus of the onion. Electron shells are very similar. As you move away from the nucleus, each shell gets progressively larger and maintains a given distance away from the nucleus of the atom.

Currently, there are believed to be seven primary electron shells surrounding an atom (fig. 5-2). Each shell is named using the lowercase letter “n” and a number designation. To calculate the maximum number of electrons a principal electron shell can hold, use this formula:

$$\text{Maximum \# of electrons per shell} = 2n^2$$

where

n corresponds to the shell number.

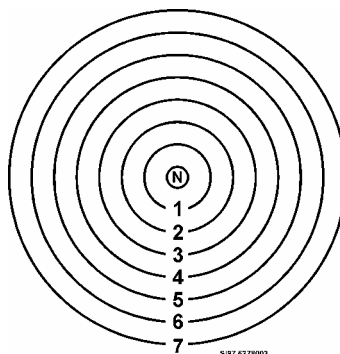


Figure 5-2. Electron shells by numerical designation.

For instance, to calculate the amount of electrons in the first electron shell: $n=1$, so $2(1^2)=2$. You have just calculated that the first electron shell can hold up to two electrons. The table below gives the number designations for the primary electron shells and the maximum (theoretical) number of electrons the shell may hold.

Shell Number	Max. # of Electrons	Shell Calculation
1	2	$2(1^2)$
2	8	$2(2^2)$
3	18	$2(3^2)$
4	32	$2(4^2)$
5	50	$2(5^2)$
6	72	$2(6^2)$
7	98	$2(7^2)$

Electrons must fill or partially fill lower energy levels before starting to fill higher levels. This is illustrated in figure 5-3 where the sodium atom has 11 electrons that are circling the nucleus. By applying the principles of the table above, you can see that all electrons must fill their respective energy shells in succession. The outermost shell of any atom containing electrons is the *valence* shell; this shell contains the “valence electrons.” The valence electrons are responsible for an atom’s chemical properties, which we discuss further when you learn about chemical bonding.

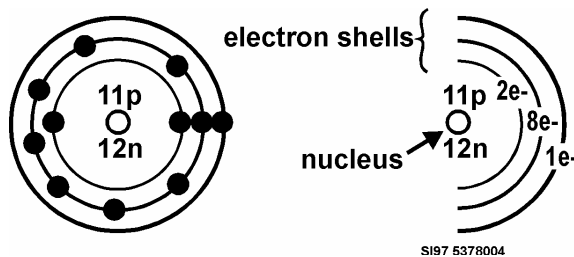


Figure 5-3. Sodium atom.

Valence

Valence we define as “the number of electrons gained, lost, or shared by an atom as it tries to satisfy the needs of its valence shell.” To put it more simply, valence is the combining power of an element. The valence may be either positive or negative, depending on whether the atom has gained or lost electrons. When atoms of different elements join to form compounds, the sum of the valences must be zero since compounds, like atoms, are electrically neutral.

For example, the hydrogen atom can give up one electron from its valence shell. When it gives up an electron, you say it has a valence of +1. The oxygen atom must borrow or receive two electrons in order to complete its valence shell. When it receives two electrons, you say it has a valence of -2. When hydrogen and oxygen combine, they form the molecule we know as water, which is electrically neutral. Valence you can determine from knowledge of an atom’s energy shell population, from the knowledge about specific compounds that elements join to form, or from a periodic chart of elements found in most basic chemistry books.

Characteristics of the atom

The present picture of the atom is that of a very heavy (relative to size), compact, positively charged center called the nucleus. The negatively charged electrons rapidly circle the nucleus in their respective shells. The simplest atom is that of hydrogen. Its nucleus consists of a single proton surrounded by one electron in the first energy level ($n = 1$). The helium atom has two protons and two neutrons in the nucleus; this nucleus is surrounded by two electrons.

Electrical neutrality

All uncombined atoms are electrically neutral. As you may recall, this means that there must always be an equal number of electrons (–) and protons (+) in an atom. When atoms gain or lose electrons, they become charged particles called *ions*. Ions are formed during chemical changes and have different properties from the atoms they originated from. You will learn more about ions later.

Atomic mass

Determine the mass of an atom by adding up the masses of all the particles in an atom. Remember, you do not include the electrons in this calculation. Therefore, the atomic mass, or AMU, is simply the sum of the number of protons and neutrons.

$$\text{Atomic mass (AMU)} = p + n$$

For example, the atomic mass of hydrogen is one ($1_p + 0_n$), and for helium it is four ($2_p + 2_n$). A further illustration is the carbon atom, which contains 6 protons (atomic number = 6), 6 neutrons, and 6 electrons. When you use the formula listed above, you see that the atomic mass of carbon is 12.

$$6_p + 6_n = 12 \text{ (the atomic mass of carbon)}$$

Referring to figure 5–4 allows you to visualize what you have just read and hopefully clarify these points.

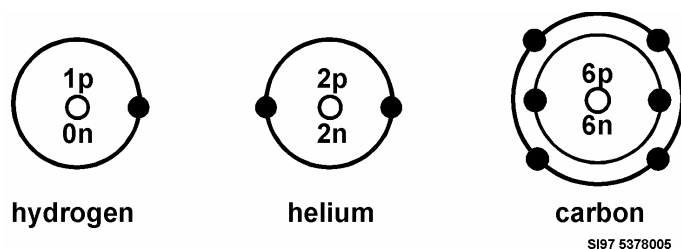


Figure 5–4. Hydrogen, helium, and carbon atoms.

Isotopes

Isotopes are atoms of the same element that have the same atomic number but *different atomic masses*. Since the atomic number is the same, these atoms have the same number of protons in their nuclei. They must therefore *differ in the number of neutrons* they each possess. For example, there are three known varieties of hydrogen (fig. 5-5). Note that the atomic number in each case is 1 (therefore, they are all hydrogen atoms), but that the atomic mass varies from 1 to 3. All three are isotopes of hydrogen, not just the last two, which are rarer types. Since the number of electrons is the same, isotopes usually have the same chemical properties. Virtually all elements have isotopes resulting in atomic weights for elements that are not whole numbers. The average atomic weight of an element and its isotopes results in the fractionation.

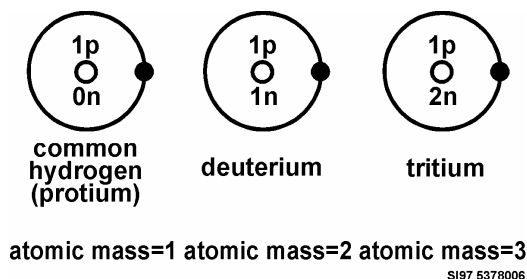


Figure 5-5. Hydrogen isotopes.

Atomic weight

The atomic weight of an element scientists define as “its weight compared to that of the carbon-12 isotope (^{12}C), which is 12,000.” For example, helium weighs about one-third as much as carbon and has an atomic weight of 4.0026. There are several differences between atomic mass and atomic weight:

- Atomic mass refers to one atom of an element, while atomic weight refers to the element itself (many atoms).
- The unit of atomic mass is the AMU, while atomic weight is grams.
- The AMU must be a whole number. The atomic weight is the *average* weight of all isotopes and accordingly may not be an exact whole number.

To illustrate this point, refer to the chlorine atoms in figure 5-6. As you can see, the two chlorine isotopes have *atomic masses* of 35 and 37 AMUs, respectively. The *atomic weight* of the element of chlorine is 35.453 grams. This *fractional atomic weight* comes about because chlorine exists as a mixture of both isotopes in nature. The 35-isotope of chlorine occurs about 75% of the time, while the other 25% is the 37-isotope chlorine. Thus, the atomic weight of 35.453 represents the average weights of both isotopes, based upon the percentage of each present.

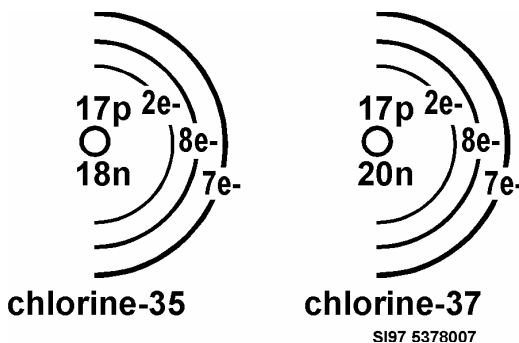


Figure 5-6. Isotopes of chlorine.

The advantage of using atomic weight instead of atomic mass is that you could easily weigh out 12 grams of carbon. If you wanted to weigh out 12 AMUs of carbon, that would present a substantial challenge.

020. How elements combine to form compounds and mixtures

Elements are the foundation of everything you will do in clinical chemistry, from analyzing a patient's specimen to mixing a reagent for use in testing. Most of the reagents you will use in the laboratory will be made from combinations of elements joined to form compounds. To use these compounds, you need to understand how elements combine and interact with each other. Let's examine how elements combine to form new substances.

Chemical symbols

Scientists use abbreviations of element names to create *chemical symbols*. A chemical symbol consists of a letter or pair of letters representing one atom of an element. We always write the first letter of a chemical symbol as a capital letter and the second letter (if needed) as a lowercase letter. For example, the chemical symbol for sodium chloride is NaCl and the chemical symbol for water is H₂O. For more information regarding chemical symbols, refer to the periodic table of elements in appendix A.

Molecule

A molecule is the smallest particle of an element or compound having all of its chemical and physical properties. Molecules of an element contain one or more atoms of the *same* element, while molecules of a compound contain at least one atom (or more) of two or more different elements. When a molecule of an element consists of only one atom, then an atom and a molecule of that element are identical.

Molecules of elements

Elements we can classify as *monatomic*, *diatomic*, or *triatomic*, according to whether they have one, two, or three atoms in each molecule.

Monatomic

A monatomic element has only *one* atom in each of its molecules. An example of this would be a molecule of helium (He). The helium atom and the helium molecule are identical. Most elements fall into this category.

Diatomic

Each molecule of oxygen (O₂) contains *two* atoms of oxygen. The oxygen atom (O) and the oxygen molecule are not the same. They have very different chemical and physical properties. O₂ is a stable, colorless, odorless gas, while the oxygen atom is unstable and immediately combines with other atoms. Hydrogen, nitrogen, fluorine, and chlorine are also diatomic elements.

Triatomic

A molecule of ozone (O₃) contains *three* atoms of oxygen. Molecules of ozone have different properties (it is an unstable, bluish gas with a pungent odor) than either oxygen molecules or atoms.

Mixtures

A mixture is a substance made up of two or more elements or compounds that have been physically mixed. Unlike a compound, no chemical reaction has taken place between the parts of the mixture. Each element or compound does not lose its original chemical properties while in the mixture. Generally, mixtures can be separated into individual compounds by physical means. Water added to a salt and sand mixture dissolves the salt. By filtering this mixture, we can remove the sand; then, applying heat evaporates the water, leaving the salt.

Compounds

A chemical compound is a substance made up of two or more elements that are chemically united in definite proportions by weight. Its properties are different from those of the elements forming the compound. A molecule of this new unit is the smallest particle of the compound that can exist. Here are some examples of common molecules for you to look at:

- A molecule of water (H_2O) contains three atoms—one of oxygen (O) and two of hydrogen (H).
- A molecule of sodium chloride (NaCl) contains only two atoms—one of sodium (Na) and one of chlorine (Cl).
- A molecule of sulfuric acid (H_2SO_4) contains seven atoms—two of hydrogen (H), one of sulfur (S), and four of oxygen (O).

Molecular composition

Compounds have a definite molecular composition by weight. Water is an example of a compound; it can be decomposed by electrolysis. When you decompose water using an electric current, you find that 88.81% of the water by weight is oxygen and that the rest is hydrogen. It is a law in chemistry that the quantity of one element needed to combine with another element is a fixed ratio by weight for a given compound. This we refer to as the *law of definite proportions*. Put more simply, a fixed weight of one element will combine with the fixed weight of another element to form a new compound. Sometimes an element can combine to form different compounds in simple multiples of this fixed weight. For example, the weight of oxygen in hydrogen peroxide (H_2O_2) is twice the weight of oxygen in water, but the weight of hydrogen stays the same.

Bonding theory

Compounds are formed from elements by bonding when an atom fills its valence shell. Remember that the valence shell is the outermost electron shell of an atom. The valence shell is said to be “complete” or “satisfied” when it has either zero or eight electrons in it (except for the first shell, which is complete with two electrons).

Rule of eight (octet rule)

Our entire bonding theory is based on the rule of eight, which is as follows: *Atoms always combine in such a way as to complete their valence shells*. They can do this by gaining, losing, or sharing electrons. The only exception to this rule is the first energy shell, which is satisfied with only two electrons, since this is the maximum number it can hold. Atoms that already have eight electrons in their valence shell are inert. They do not form compounds.

Ions

When an atom loses or gains electrons, it becomes an ion. An ion, therefore, is a charged atom. A positively charged ion we call a *cation* (loses one or more electrons), and a negatively charged ion we call an *anion* (gains one or more electrons). The attraction between oppositely charged ions is what binds the compounds together.

Types of bonding

Although it is categorically acceptable to describe the types of bonding, we must point out that no compound is formed exclusively by only one type of bond.

Ionic (or electrovalent) bonding

Ionic or electrovalent bonding occurs when atoms form compounds by transferring one of more electrons. This transfer creates ions that attract one another. The atoms combining in this manner must be very different in their physical and chemical properties.

For example, look at a metal reacting with a nonmetal. The metal loses one or more electrons, and the nonmetal gains these electrons. The result is that all atoms have their valence shells satisfied. In electrovalent bonding, electrons from the valence orbit are transferred from one atom to another. A compound is formed from the two elements bound together by the electrovalent bond. This occurs in the reaction between sodium and chlorine. When these two elements combine, they form a new compound called sodium chloride (NaCl), or what we commonly refer to as salt. As we show in figure 5-7, sodium has only one electron in its outermost orbit; chlorine has seven. In seeking stability, chlorine needs eight electrons in the outer orbit. The single valence electron of sodium is given up into the valence shell of chlorine. The compound formed now has eight electrons in the outer orbit and is stable.

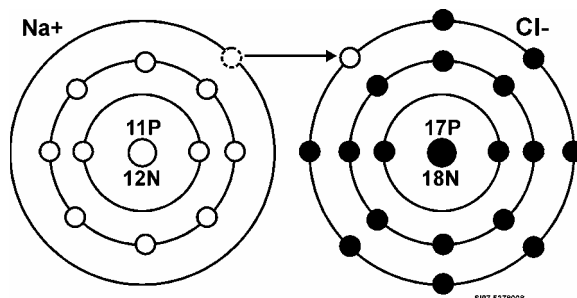


Figure 5-7. Electrovalent bonding in the NaCl molecule.

Covalent bonding

In covalent bonding, each atom donates one or more valence electrons to be shared equally by the two. An example of covalent bonding is the reaction between hydrogen and chlorine. Hydrogen chloride in the pure (gaseous) state has a covalent bond, but hydrochloric acid is an electrovalent compound in water. An atom of hydrogen reacts with an atom of chlorine to yield a molecule of HCl. Figure 5-8 shows how hydrogen donates one valence electron and the chlorine donates seven to make a covalently bonded stable compound with eight electrons in its outermost orbit.

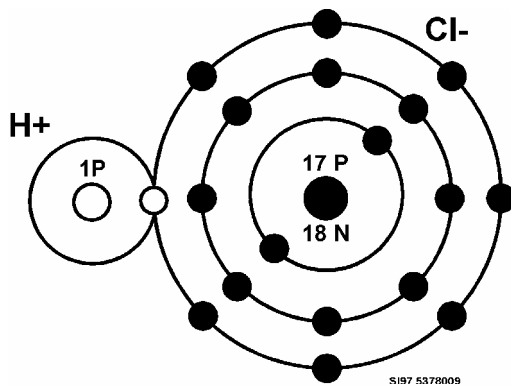


Figure 5-8. Covalent bonding in the HCl molecule.

Coordinate covalent bonding

The coordinate covalent bond is essentially the same as the covalent bond except that one atom donates all the electrons to be shared. A good example of coordinate covalent bonding is represented by the compound formed by combining sulfur and oxygen (fig. 5-9). In this reaction, the sulfur atom provides two electrons to each of the three atoms of oxygen. Only one oxygen atom contributes to the completion of the sulfur valence shell. A compound with eight valence electrons in the outer shell, sulfur trioxide, is formed by coordinate covalent bonding.

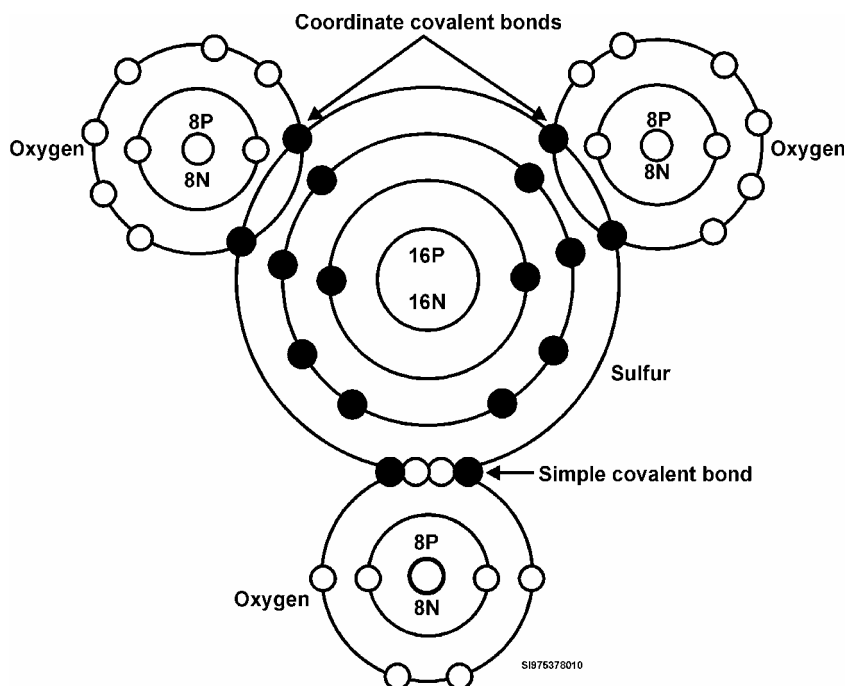


Figure 5-9. Coordinate covalent bonding in the SO_3 molecule.

Nonpolar covalent bonding

A nonpolar covalent bond is formed when two like atoms share electrons—for example, chlorine (Cl_2). The two chloride atoms are identical and the electrons are shared equally between them.

Polar covalent bonding

Polar covalent bonds occur when the electronegative charge is greater in one atom than in the other. In this case, the orbiting electrons that are being shared are not being shared equally; they are closer to one atom than the other.

Chemical formulas

By now, you are probably familiar with some of the symbols used to represent different elements. As time goes on, you will become familiar with those that are commonly used in the clinical laboratory setting. Although you can find these symbols in the periodic table of elements (appendix A), you primarily see these on the labels of the reagent and chemical bottles used in your daily activities. Normally in the clinical laboratory setting, you are not required to calculate or write formulas, so we don't cover these items in depth here. However, be aware of what chemical formulas are and what they represent.

Formulas are the combinations of symbols representing compounds. Compounds are named from the formula, and the formula is derived on the basis of the valences of the two or more elements entering into the reaction. The valences of the elements combining chemically determine how much of each element (and thus the formula) is required for the new compound to be formed. The compound must be electrically neutral. A chemical formula consists of a symbol or group of symbols, with the proper subscripts, to represent one molecule of an element or compound.

Factors that affect chemical reactions

There are a wide variety of chemical reactions that you will observe taking place as you perform your duties. Some are reversible, either partially or completely, while others are irreversible. There are certain factors that may influence the outcome of your chemical reactions. Knowing these factors can

help you predict the outcome of your reaction or help you troubleshoot a problem if the reaction you observe is not what you expected. The factors you are about to read about are the main points for factors affecting chemical reactions; the listing is not all-encompassing.

Le Chatelier's principle

Le Chatelier's principle states that a system in equilibrium reacts to a stress by establishing a new equilibrium. Some of the factors that may affect the equilibrium are temperature, light, pressure, and catalysts.

Temperature

In the majority of cases, a chemical reaction rate increases as you increase the temperature. When temperature increases, the molecules move faster (colliding more frequently), resulting in an increased reaction rate. Decreasing temperature has the opposite effect on a chemical reaction.

Light and pressure

Some reactions are accelerated by the addition of light energy. It is for this reason that you keep reagents in brown bottles. The addition of pressure primarily applies to when you are working with gases. Pressure is based on the corresponding volume changes in the reactants or compounds formed.

Catalysts

The effects caused by catalysts are probably of more interest to the chemistry technician than any other factor in a chemical reaction. A catalyst is a substance that speeds up or slows down a chemical reaction without being changed itself. Enzymes fall into the category of biocatalysts, or catalysts that activate or accelerate biological processes.

Concentration

In addition to Le Chatelier's factors mentioned above, the concentration of the reacting substances may also influence the rate of a chemical reaction.

021. Acids, bases, salts, and solutions

Many of the procedures you will perform rely on the interactions of these substances. Sodium chloride is essential to blood banking while acids and bases interact in a variety of chemistry procedures. Understanding the properties of these substances helps you understand laboratory testing principles. Let's take a look at what they are and how they work, but let's not forget to exercise safety due to the caustic nature of some of these substances.

Acids

It has been commonly accepted that acids are substances that yield or donate hydrogen ions (H^+) in a water solution. The Brønsted-Lowry theory defines an acid as a substance that donates a proton. This definition is based upon the fact that a hydrogen ion results when a hydrogen atom loses its only electron, leaving a single proton behind. In effect, both definitions of acid essentially mean the same thing. Acids can be found as solids, gases, or liquids. When placed into a solution, strong acids are completely ionized while weak acids are only partially ionized. Acids are classified based upon how many hydrogen ions they yield when placed in solution.

Bases

Bases are defined as "substances that yield hydroxide (OH^-) ions in a water solution." Brønsted describes a base as a substance that accepts protons. The basic difference chemically between an acid and a base is that an acid donates protons while a base accepts them. Although bases are not binary compounds, they do have the *-ide* suffix. For example, consider the following bases: sodium hydroxide (NaOH), potassium hydroxide (KOH), and lithium hydroxide (LiOH).

Indicators

Many laboratory tests are measured based upon reactions resulting in a color change. The amount of color change may be directly or indirectly proportional to the amount of the analyte you are testing. Indicators are substances that produce a color when they react with certain compounds. Depending on the type used, indicators determine what color your reaction will be. A common example of an indicator used in the laboratory is litmus paper. Blue litmus paper turns red when reacting with acids, and red litmus paper turns blue when exposed to a base.

Salts

When you combine acids and bases, a process known as *neutralization* occurs. The acid and base effectively cancel or neutralize each other. When this happens, the acid and the base combine to form a salt and water. Salts are compounds that are formed when one or more of the hydrogen ions of an acid are replaced by a cation, or when one or more of the hydroxide ions of a base are replaced by an anion.

As you will learn later, salts are extremely important in body chemistry with regard to maintaining electrolyte balances and other bodily functions. The table below lists some examples of salt functions in the body.

Type of Salt	Function
Iron salts	Formation of hemoglobin
Iodine salts	Thyroid gland
Calcium salts	Bones and teeth
Sodium and potassium salts	Acid-base balance

Solutions and solution concentrations

We cannot overemphasize the importance of pure, accurate solutions in the laboratory setting. The accuracy of the test results you obtain depends on the reagents you prepare. These solutions are not the result of magic, but rather from the intelligent, exacting application of solution principles. You need to be able to calculate solutions in various percentages, adjust the pH of your solution, and determine how certain variables such as purity will affect your final product.

Nature of solutions

A solution we define as “the homogenous mixture of two or more substances evenly distributed in a solvent.” Solutions are divided into two parts—the *solute* and the *solvent*. The solute is a solid, liquid, or gaseous material that has been dissolved, and the solvent is the liquid material in which the solute has been dissolved. A good example of this principle is salt water. The salt crystal is the solute, and when we place it into the solvent (water), salt water is formed.

Most of the solutions used in the clinical laboratory are solids in liquids or liquids in liquids. The following properties are those that make up true solutions:

- They consist of a soluble material or materials (solute) dissolved in a liquid (solvent).
- They must have a variable composition.
- They may be either colored or colorless, but they are usually transparent.
- They are homogenous (that is, they mix well and the separate components cannot be distinguished from one another).
- They do not settle.
- They can be separated by physical means (evaporation, electrolysis, etc.).
- They are able to pass through filter paper without changing.

If all of the above criteria are met, then you may safely say that you have a solution. There are several factors, however, that you must take into account when dealing with and creating solutions. These factors are shown in the table below.

Variable	Result
Temperature	Solid solutes are more soluble in hot water than in cold. Gases are usually less soluble as the temperature increases.
Pressure	Little or no effect on solid or liquid solutes. With gases, the greater the pressure, the greater the solubility.
Surface area	Affects the rate of dissolution. The greater the area, the quicker a solute dissolves.
Stirring	Increases the rate at which a solute dissolves. This mainly affects solids.
Concentration	When the solute and solvent are first mixed, the rate of dissolving is at its maximum. As the concentration of the solution increases (increased solute), the rate of dissolving decreases greatly.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

019. Terms relating to atomic theory

Read the items below and determine the correct term for each statement. Locate and circle the term in the word-find puzzle below. Terms may be listed horizontally, vertically, or diagonally.

1. The building block of all elements.
2. A subatomic particle with a positive electrical charge.
3. A subatomic particle that is electrically neutral.
4. A subatomic particle that is negatively charged.
5. What is the maximum number of electrons that can occupy the “third” electron shell of an atom?
6. If there are six electrons in the carbon atom, how many can occupy the “second” electron shell?
7. What do we call the outermost electron shell of an atom?
8. These are formed during chemical changes and have different properties from the atoms they originated from.

9. What atomic characteristic do we determine by adding up the number of protons and neutrons in an atom?
10. These are atoms of the same element that have the same atomic numbers but different atomic masses.
11. What atomic characteristic do we define as the average weight of all the isotopes of an element?

J	A	B	A	T	O	M	S	M	P	A	X	A
T	H	I	V	M	I	W	Z	X	C	E	B	U
M	P	P	I	M	A	S	S	O	F	O	U	R
B	A	R	Y	S	Y	M	A	C	T	M	K	D
I	S	D	O	A	B	U	W	E	I	G	H	T
P	O	M	I	T	N	U	B	Y	V	T	C	E
Z	W	A	Q	L	O	S	K	I	J	N	H	Y
G	T	F	R	D	E	N	S	E	W	E	Q	Z
X	W	C	D	E	V	F	R	I	B	U	U	T
E	E	N	Y	H	U	M	J	G	I	T	O	L
P	L	L	C	R	D	Y	U	H	Q	R	A	Z
R	E	Y	V	U	H	K	N	T	S	O	A	R
T	C	S	H	A	K	M	J	E	Q	N	E	R
Y	T	I	H	N	L	B	F	E	S	A	Z	X
I	R	O	P	K	J	E	S	N	V	B	I	I
E	O	Q	Z	E	D	F	N	U	I	L	D	O
S	N	X	C	J	E	S	Q	C	O	K	M	N
U	Y	E	S	X	V	G	O	H	E	N	O	S
I	S	O	T	O	P	E	S	U	T	R	E	X
D	R	A	H	C	I	R	R	E	G	O	R	M

020. How elements combine to form compounds and mixtures

1. What does a chemical symbol consist of and what does it represent?

2. What is the difference between molecules of an element and molecules of a compound?
3. What do the terms “monatomic,” “diatomic,” and “triatomic” signify in relation to molecules?
4. What is a compound, and what can be said about its properties compared to the elements from which it was formed?
5. The quantity of one element needed to combine with another element in a fixed ratio we refer to as which chemical law?
6. What are cations and anions, and how do they relate to chemical bonding?
7. What term defines combining element symbols (examples: NaCl, H₂O) to represent compounds?
8. What factors may affect chemical reactions?

021. Acids, bases, salts, and solutions

1. Define what an acid is, and describe how acids are classified.
2. Define what a base is, and describe how it differs from an acid.
3. Describe what an indicator is, and name one that is commonly used in the laboratory.
4. Describe how salts are formed.
5. Give two examples of salts and where they function in the human body.
6. What is the definition of a solution?

7. What is the difference between a solute and a solvent?
8. List three properties of a true solution.
9. What are the variables that may affect the solubility of a solution, and what is their result on the solution?

5-2. Components of Clinical Chemistry

Clinical chemistry, although a science in itself, is made up of several branches of other chemistry disciplines. Each type of chemistry lends a little bit to the larger picture known as clinical chemistry. As a laboratory technician, you enter into the picture when you apply each of these factions to analyze specimens and validate test results.

022. Inorganic and organic chemistry

When you start to think about chemistry, a couple of stereotypes come to mind: the young kid whose experiment goes awry and who stink-bombs his family out of the house, or perhaps the mad scientist creating life in a dark, dingy, dungeon laboratory. Your exposure to chemistry will be far removed from these examples (or should be, anyway) after you study this course. Let's start you off with a look at two of the main types of chemistry—inorganic and organic.

Inorganic chemistry

Inorganic chemistry deals with the elements themselves and mineral matter. As a general rule, inorganic chemistry is a “lifeless” chemistry; very few inorganic compounds contain carbon (with few exceptions). Most inorganic compounds are solid and dissolve easily in water. In addition, most inorganic compounds use ionic bonds to bind themselves together. These ionic bonds cause inorganic substances to have high melting and boiling points.

Organic chemistry

This type of chemistry deals with virtually all carbon-based compounds. A few, however, are excluded from the organic classification because their properties are more closely related to those of inorganic substances. Some of these special kinds of carbon compounds include metal carbides, carbon oxides, and metal carbonates.

Eighteenth-century chemists used the term “organic” to describe substances obtained from living sources (plants and animals). At that time, no one had been able to create an organic material out of inorganic substances. The chemists reasoned that organic compounds were formed by some type of “vital force” in nature and only nature could produce organic compounds.

In 1828 a German chemist by the name of Friedrich Wöhler conducted an experiment that later proved to be the death sentence of the vital force theory. While trying to prepare ammonium cyanate by heating cyanic acid and ammonia, he obtained a white, crystalline substance that he identified as urea. Urea, he knew, was an organic substance, which is a product of metabolism. His work showed that no vital force (other than skill and knowledge) was needed to create organic chemicals.

Currently, organic chemistry is a branch of chemistry that deals with carbon compounds regardless of whether or not they originate from a life form. Organic molecules may also contain hydrogen, oxygen, nitrogen, sulfur, chlorine, bromine, and iodine in addition to carbon. Between naturally

occurring and man-made compounds, over 5 million organic compounds are known to exist. This number is significant when compared to the 100,000 or so known inorganic compounds.

The majority of organic compounds are held together by covalent bonds. These covalent bonds are what make organic compounds have low melting and boiling points. While there are many different organic compounds, they are divided into relatively few classes. The classes of organic compounds are based on the structure or functional group they contain.

Hydrocarbons

Hydrocarbons are the basis of all organic compounds. They are made up solely of carbon and hydrogen, and the carbon may be in straight chains, branched chains, or cyclic. Using their structure as a basis, we can divide hydrocarbons into two classes—*aliphatic* and *aromatic*. The difference between aliphatic and aromatic hydrocarbons we can determine by the presence (or lack) of the benzene group or ring. Aliphatic hydrocarbons do not contain the benzene group or ring, while aromatic hydrocarbons contain one or more benzene rings.

Functional groups

A functional group is the part of a molecule that has a special arrangement of atoms. This arrangement is responsible for the chemical behavior of the parent molecule. Any molecules with the same functional groups react the same under similar circumstances or conditions. By knowing the characteristic properties of a few functional groups, you can understand the workings of many organic compounds. The functional groups of organic chemistry are varied and include the following: alcohol; aldehyde and ketones; esters, sterols and phenols; as well as amines and amides.

023. Analytical chemistry and biochemistry

To further understand clinical chemistry, you sometimes need to be able to take a substance apart and see its composition. This is where analytical chemistry comes into play. At other times, you need to understand the chemical reactions that take place within living tissue. The chemistry dealing with biological processes we know as biochemistry. Both analytical chemistry and biochemistry will play key roles in your duties as a laboratory technician.

Analytical chemistry

Analytical chemistry is concerned with the qualitative (what is it made up of) analysis and quantitative (how much is there) analysis of the elements in a compound. This is done by forcing a compound to break down into its various constituents or parts. Once this is accomplished, the constituents are then measured. This is important when reporting a test result to a physician because he or she may base the treatment or diagnosis on the amount of a particular analyte or group of analytes.

Biochemistry

Molecules by themselves do not possess life; yet, when they are combined in the right format, life is present. In biochemistry, the objective is to understand these combinations and what influences (good or bad) may affect them. Biochemistry is the chemistry of living organisms and their vital processes; sometimes we also refer to it as *physiological* chemistry. The scope of biochemistry includes things such as an organism's growth, digestion, respiration, metabolism, and reproduction. All life as we know it depends on four major classes of biomolecules: carbohydrates, lipids, proteins, and nucleic acids.

Carbohydrates

Carbohydrates are polyhydroxy aldehydes or polyhydroxy ketones or compounds that yield these substances if they are hydrolyzed. "What does that mean to me?" you may be wondering. Not much, except that you need to know that carbohydrates are of major importance to plants and animals. It has been estimated that more than half of all of the world's organic carbon atoms are found in

carbohydrates. Simple carbohydrate molecules are created by chlorophyll-containing plants through the process of photosynthesis. Animals (including humans) are incapable of making their own carbohydrates and must get their carbohydrates from eating plants.

Humans use carbohydrates for many purposes, but principally for food. Carbohydrates are used by the body primarily for energy and also for the carbon atoms they contain since these aid the synthesis of other compounds. Carbohydrates make up about 65% of the typical human diet. In addition to the body's energy cycle, carbohydrates are also found in nucleic acids and connective tissue.

Carbohydrates exist as sugars, starches, and cellulose. The simplest of these compounds are the sugars, also called *saccharides*. Sugars have names ending in “-ose,” such as glucose, sucrose, and maltose. Carbohydrates are classified as monosaccharides, disaccharides, oligosaccharides, and polysaccharides according to the number of monosaccharide units linked together to form a molecule. A *monosaccharide* is a carbohydrate that cannot be hydrolyzed (broken down) into a simpler carbohydrate unit. Glucose is a common example of a monosaccharide. A *disaccharide* is a carbohydrate that can be hydrolyzed into two monosaccharides. Simple table sugar, or sucrose, is an example of a disaccharide. *Oligosaccharides* are carbohydrates made up of three to 10 monosaccharides. *Polysaccharides* are also made up of monosaccharides linked together, but these may number into the thousands. Polysaccharides are the more complex carbohydrates such as starches, glycogen, and cellulose.

Lipids

Lipids are organic substances that are insoluble in water and are found in living organisms. The most abundant of the lipids are fats and oils. Animals (including humans) store some energy in the form of carbohydrates; however, the bulk of their energy is stored in the form of fats. When the body burns fat to produce energy, twice as much energy is produced as by burning carbohydrates (about 9 kilocalories per gram [kcal/g] for fats versus about 4 kcal/g for carbohydrates).

Fats and oils are esters formed of long-chain aliphatic carboxylic acids and are commonly referred to as *glycerides*. Fats are glycerides that are usually solid at room temperature, while oils are liquids at room temperature. Fats and oils are obtained from natural sources. As a general rule, fats come from animal sources, while oils come from vegetable sources. The chart below shows some common examples of fats and oils.

Animal Fats	Vegetable Oils
Beef tallow	Corn oil
Butter	Olive oil
Lard	Peanut oil

In addition to fats and oils, other classes of lipids include phospholipids, glycolipids, and steroids. *Phospholipids* are found in all animal and vegetable cells and are abundant in the brain, spinal cord, and liver. *Glycolipids*, also known as *cerebrosides*, are found primarily in the brain (these make up 7% of the dry weight of the brain) and at nerve synapses. *Steroids* are important to the body's chemistry because this group also includes many hormones. Cholesterol is an example of a steroid in the body; in fact, it is the most abundant of the body steroids. We cover cholesterol later.

Proteins

Depending on whom you are talking to, some people feel that proteins are the most important of all the biological compounds. The term “protein” is taken from the Greek word *proteios*, which means “of first importance.” About 15% of human body weight is protein; proteins are present in all body tissue. Listed below are just some of the functions proteins perform in the body:

- Structure—Proteins are the main constituents of bone, skin, hair, and nails.

- **Catalysis**—Just about all reactions that take place within the body are catalyzed by proteins called enzymes. **Movement**—Every time you move a muscle (scratch, blink, run, etc.), you contract or expand your muscles. Muscles are made up of proteins called myosin and actin.
- **Transport**—Some proteins transport molecules across cell membranes, while others, such as hemoglobin, carry oxygen from the lungs to the tissues and carbon dioxide from the tissues to the lungs.
- **Hormones**—Many hormones are proteins—insulin, epinephrine, and human growth hormone, just to name a few.
- **Protection**—When an antigen (an outside protein) invades the body, the body makes its own protein (called an antibody) to counteract the foreign protein. Blood clotting is another protective function carried about by a protein (called fibrinogen).
- **Storage**—Some proteins are used to store materials. In the liver, a protein known as ferritin stores iron.

These are not the only functions of proteins, but they are examples of some of the most important.

A typical cell is made up of about 9,000 different proteins; the human body has about 100,000 different proteins. Although there are so many different kinds of proteins, they all basically have the same kind of structure. Proteins are linear chains of *amino acids*. While organic chemists are capable of creating thousands of amino acids, only 20 make up all the various proteins in the body. As tissues in the body break down, they must constantly be replaced or repaired. The body picks the desired amino acids out of the bloodstream to synthesize or build the required protein. The synthesis of proteins is controlled by nucleic acids.

Nucleic acids

The basic unit of structure for all living things is the cell. Inside the cell is the nucleus, which contains chromosomes. Chromosomes are made up of proteins and nucleic acids. As you may recall, chromosomes are responsible for transmitting heredity factors from one generation of cells to the next. There are two types of nucleic acids—deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). Only DNA carries the hereditary information. This information tells the cell which proteins to manufacture. As a laboratory technician, your interest in nucleic acids becomes evident in patients suffering from genetic abnormalities. Hemophilia, sickle-cell anemia, color blindness, and other impaired genetic states are caused due to a lack of certain proteins (proteins that are found in “normal” individuals).

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

022. Inorganic and organic chemistry

1. Match each item in column B with the statement it relates to in column A by placing the letter of the column B item beside the number of the column A item that most describes it. Each item in column B may be used once, more than once, or not at all.

Column A

- ____ (1) This chemistry deals with the elements themselves and mineral matter.
- ____ (2) Most are solid and dissolve easily in water.
- ____ (3) This chemistry deals with virtually all carbon-based compounds.
- ____ (4) This theory stated that only a “vital force” in nature could create organic compounds.

Column B

- a. Vital force theory.
- b. Inorganic chemistry.
- c. Organic chemistry.
- d. Inorganic compounds.

2. Describe the type of bonding used in inorganic and organic compounds.
3. What are the two classes of hydrocarbons? How do they differ?

023. Analytical chemistry and biochemistry

1. Briefly describe analytical chemistry and biochemistry.
2. Explain where carbohydrates come from and how animals get them.
3. Carbohydrates exist in what three forms?
4. Explain what mono-, di-, oligo-, and polysaccharides are.
5. What organic substances are found most abundantly as fats and oils and are insoluble in water?
6. Describe the difference between fats and oils.
7. Briefly describe phospholipids, glycolipids, and steroids.
8. What term is taken from the Greek word meaning “of first importance”?
9. List at least three functions proteins perform in the body.
10. What do proteins consist of?
11. What are the two types of nucleic acids, and which type carries the hereditary information?

5-3. Laboratory Measurements

Some sort of measurement controls just about every aspect of daily life. Your alarm clock measures time and tells you when to get up; a recipe tells you how much of a certain ingredient to use to make a cake. You measure the amount of gasoline you have to put into your car, the weight of fruits and vegetables you buy at the store, and so forth; no matter where you look, you interact with measurements. Your work in the laboratory is no exception; in fact, it is probably more dependent on measurements than other aspects of your life.

024. Measurement systems

In order to have a measurement, you need to have two things: a number and a unit. A number without a unit for reference is probably useless. Take, for example, a bag of microwave popcorn. If the directions just said to cook it for “3,” you would have several options with several outcomes. Cooking it for 3 seconds would not do much good, cooking it for 3 minutes would probably be pretty good, but cook it for 3 hours and you will be explaining to the fire department how you managed to start the fire. There are so many units and applications that numbers alone are not enough. You also need to have a measurement unit as a point of reference.

English

In the United States, the primary means of measurement are based on the English system of units. These are the units you probably grew up with—pounds, gallons, miles, and so on. As time goes on, however, the conversion of this measurement system to the one being used by the rest of the world—the metric system—is slowly taking place. Manufacturers are beginning to convert their products to the metric system and often have both English and metric measurements listed on their label (look at a soda can, for example). In the laboratory, however, the English system is rarely used and the scientific community has been using the metric system all along. Be aware that the English system does exist, however. There will be rare instances when you may have to convert from an English unit of measurement to its metric equivalent.

Metric

The metric system can trace its beginnings back to France about 1800 and has since spread throughout the world. The metric system is specifically designed for use with decimal notation. This system has one primary unit for each quantitative property (mass, length, volume) and a set of prefixes. Each prefix designates a factor that must be applied to the primary unit. By combining the prefix and primary unit, you may produce larger or smaller units of a property. Before you go any further, review the table below. Take note of the prefixes and the way their given factor affects your primary unit (showing a total larger than your primary unit or smaller than your primary unit).

Prefix	Exponential	Symbol	Decimal
tera	10^{12}	T	1,000,000,000,000.0
giga	10^9	G	1,000,000,000.0
mega	10^6	M	1,000,000.0
kilo	10^3	k	1,000.0
hecto	10^2	h	100.0
deca	10^1	da	10.0
*Primary unit	10^0	g, L or l, m	1.0
deci	10^{-1}	d	0.1
centi	10^{-2}	c	0.01
milli	10^{-3}	m	0.001
micro	10^{-6}	μ	0.000001
nano	10^{-9}	n	0.00000001

Prefix	Exponential	Symbol	Decimal
pico	10^{-12}	p	0.000000000001
*Primary unit = gram (g), liter (L or l), meter (m)			

The metric system prefixes do nothing more than describe your primary unit. The primary units are what you are trying to measure. If you are measuring weight or mass, your primary unit is the gram; for fluids, the primary unit is the liter; and for length or volume, the primary unit is the meter. Please note that when you are dealing with liters, you can abbreviate them using either the capital letter “L” or the lowercase letter “l.” The lowercase letter “l” is the most common method in use, but there is concern that the lowercase letter “l” may be confused with the number “1.” As a general rule, you see liters expressed using the lowercase letter “l” in this and subsequent laboratory CDC volumes. Be sure to differentiate between the lowercase letter “l” and the number “1” based on the context of the question or sentence. Listed in the table below are some of the more common combinations of prefixes and primary units that you will use in the laboratory.

Multiple	Mass	Length	Volume
1,000	Kilogram (kg)	Kilometer (km)	Kiloliter (kl)
1 (primary unit)	Gram (g)	Meter (m)	Liter (L or l)
1/10	Decigram (dg)	Decimeter (dm)	Deciliter (dl)
1/100	Centigram (cg)	Centimeter (cm)	Centiliter (cl)
1/1,000	Milligram (mg)	Millimeter (mm)	Milliliter (ml)
1/1,000,000	Microgram (μg)	Micrometer (μm)	Microliter (μl)
1/1,000,000,000	Nanogram (ng)	Nanometer (nm)	Nanoliter (nl)
1/1,000,000,000,000	Picogram (pg)	Picometer (pm)	Picoliter (pl)

Système Internationale

In 1960 the international scientific community adopted another system of measurement called the *Système Internationale d’Units* (or in English, the “International System of Units.”) The *Système Internationale*, or “SI” as it is more commonly known, is based on the metric system and uses some of the metric units. SI is somewhat more restrictive than the metric system in that it favors the use of some metric units and discourages the use of others. The SI system was initially created for use in the field of physics, and later it was modified for use in laboratory work.

Where the metric system was based around primary units, the SI system is centered around *basic properties*. Each basic property is assigned one unit; these units are called *base units*. The table below shows you the base properties used in SI (what the property is being measured), the name given to the property (the base unit), and the symbol used to abbreviate the property’s name.

Property	Base Unit Name	Symbol
Mass	Kilogram	Kg
Length	Meter	M
Time	Second	S
Catalytic amount	Katal	kat
Amount of substance	Mole	mol

In order to describe properties other than the base units, you need to use combinations of the basic properties. These units of measure are called *derived units* and are derived mathematically from two or more base units. An example of a derived unit is the property of volume. Volume is the amount of space something takes up, but it is not a basic property. To describe volume, you need to show a basic

SI property in three dimensions. This you can do by defining volume as length \times length \times length, or length cubed (L^3). The table below shows examples of SI derived units.

Derived Property	Name	SI Symbol	Expressed as SI Based Units
Volume	cubic meter	m^3	m^3
Mass density	kilogram per cubic meter	kg/m^3	kg/m^3
Concentration of substance amount	mole per cubic meter	mol/m^3	mol/m^3

As your facility incorporates new equipment and techniques, be sure to watch how analyte values are reported. A great deal of confusion can be created if health-care providers are accustomed to receiving reports measured one way and then suddenly must base decisions on an unfamiliar reporting system. Always be sure to include a reference range when reporting out results. If you know ahead of time that a change in testing methods also includes a change in reporting units, conduct in-services for lab and provider staff. A brief heads-up will help minimize confusion and frustration and ensure smooth operations. The table below shows a few comparisons of chemistry analytes in conventional and SI units.

Analyte	Conventional Unit	Comparable SI Unit
Albumin	g/dl	$\mu mol/l$
Calcium	mg/dl	mmol/l
Thyroxine	$\mu g/dl$	nmol/l

Significant figures

Just about everything you do in the laboratory will be reduced to a series of numbers. Whether it is the values you report out as results, the total samples you process, or the cost of supplies you need to do your job, numbers play a big part in what you do. Regardless of how you report out your numbers (the units of measure you use), only report the numbers that have any real meaning to what you are trying to say. In order to do that, you need to understand the concept of significant figures. A *significant figure* we define as “a measured number, one in which the number of digits are known with certainty.”

Significant figures come into play based on the limitations of your instruments or equipment. *Never* report out a result that exceeds your instrument’s capabilities. For example, if your analyzer reports out glucose as a whole number, never report a result carried out to three decimal places. The so-called “gray area” where some lab technicians get into trouble over significant figures is in testing where the result is subject to interpretation. Many dipstick tests (such as urine tests) or visually read tests (such as the tablet test for glucose) require some interpretation on the part of the technician. It is quite easy for technicians to exaggerate the result based on what they “think” it is. Have you seen a technician use pH paper that has a chart listed in whole numbers only, and he or she reported out a figure with a decimal point because the color was between two points? The numbers being reported out are not truly significant numbers (the numbers after the decimal are not known for certain), yet the technician is reporting them out as if they are. Often, the health-care provider accepts what you report out at face value, so you need to be sure you are not reporting a precision you do not actually have.

Here are a few rules you need to follow when determining the significant figures in your number:

1. All nonzero digits in a number are significant. (In the number 34.56, all the digits are significant because none are zero.)
2. All zero digits between two nonzero digits are significant. (For example, in 1.01, 10.01, 100.001, and 101.101, all the digits, including the zeros, are significant.)

3. All zeros to the right of a decimal point *and* to the right of a nonzero digit are significant. (In the examples 1.00, 1.100, 10.100, and 100.00, the significant zeros to the right of the decimal indicate the precision of the number. If your method is not that precise, do not include these zeros.)
4. All zeros to the left of a nonzero digit but to the right of a decimal point are not significant if there is not a significant digit to their left. (This is the hardest rule to understand. In the examples 0.011, 0.00011, and 0.00000011, the zeros are *not* considered significant numbers. They only indicate the decimal place of the other digits in the number and do not possess an actual value themselves. If the only digit to the left of the decimal point is a zero, its sole purpose is to indicate the decimal point, so it too has no significance.)

Try your hand at a few examples for each rule before moving on to the self-test questions.

Underlined Number: Significant or Not?	Rule that Applies	Reason for Significance
<u>225.786</u>	Rule #1	All are significant because none of the digits are zero.
13 <u>0.0</u> 25 1.1 <u>00</u> 5	Rule #2	These zeros are significant because they fall between two nonzero digits.
5. <u>000</u> 20. <u>000000</u>	Rule #3	These zeros are significant because they are to the right of a nonzero digit. Zeros to the decimal right demonstrate the precision of the number.
<u>0.0</u> 1 0. <u>0000</u> 4 <u>0.000000</u> 123	Rule #4	These zeros are not significant. They are to the right of the decimal and do not have a significant digit to their left.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

024. Measurement systems

1. In the English system of measurement, what are the reporting units for weight, liquid, and distance?
2. Explain how prefixes affect the primary reporting unit in the metric system.
3. In which instances may you want to use the capital letter “L” rather than the lowercase letter “l” when abbreviating liters?
4. What is SI, and on what measurement system is it based?
5. What are the basic properties used in SI, and what are their base units called?
6. What are “derived units” in SI, and how are they obtained?

7. With regards to measurement systems, what do you do if you are implementing a new piece of equipment or technique?
8. Explain what a “significant number” is.
9. A technician reports out a urine pH as 5.5 when the visual reader only offers 5 or 6 as an acceptable choice. By reporting out this result, what has the technician done?
10. In which of the following numbers are the zeros considered significant numbers: 10.02, 3.00, and 0.02? Explain.

Answers to Self-Test Questions

019

			A ¹	T	O	M	S					
	P ²			M ⁹	A	S	S		F ⁶	O	U	R
		R										
			O				W ¹¹	E	I	G	H	T
				T								
					O					N ³		
						N		E ⁵		E		
								I		U		
	E ⁴							G		T		
	L							H		R		
	E		V ⁷					T		O		
	C			A				E		N		
	T				L			E				
	R					E		N				I ⁸
	O						N					O
	N							C				N
									E			S
I ¹⁰	S	O	T	O	P	E	S					

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020

1. A letter or pair of letters representing one atom of an element.
2. Molecules of an element contain only one or more atoms of the same element while compounds contain two or more atoms of different elements.
3.
 - (1) Monatomic molecules contain only one atom of an element. In monatomic molecules, the molecule and the atom of an element are the same.
 - (2) Diatomic molecules contain two atoms of the same element.
 - (3) Triatomic molecules contain three atoms of the same element.
4. A compound is a substance made up of two or more elements, chemically united in definite proportions by weight. A compound's properties are different from the elements from which the compound was formed.
5. The law of definite proportions.
6. Cations are positively charged ions; anions are negatively charged ions. The attraction between oppositely charged ions is what binds compounds together.
7. Chemical formulas (examples given are sodium chloride and water).
8. Temperature, light, pressure, catalysts, and concentration.

021

1. An acid is a substance that yields or donates a hydrogen ion (H^+) in a water solution. Acids are classified based upon how many hydrogen ions they yield when placed in a solution.
2. A base is a substance that yields hydroxide ions (OH^-) in a water solution. The difference between acids and bases is that an acid donates protons while a base accepts them.
3. An indicator is a substance that produces a color when it reacts with certain compounds. Litmus paper is an indicator commonly used in the laboratory.
4. When acids and bases are combined, they neutralize each other. When this happens, salt and water are formed.
5. Any two of the following:
 - (1) Iron salts—hemoglobin formation.
 - (2) Iodine salts—thyroid gland.
 - (3) Calcium salts—bones and teeth.
 - (4) Sodium and potassium salts—acid-base balance.
6. The homogenous mixture of two or more substances evenly distributed in a solvent.
7. The solute is a solid, liquid, or gaseous material that has been dissolved, and the solvent is the liquid material in which the solute has been dissolved.
8. Any three of the following:
 - (1) It consists of a solute dissolved in a solvent.
 - (2) It must have a variable composition.
 - (3) It may be either colored or colorless, but it is usually transparent.
 - (4) It is homogenous.
 - (5) It will not settle.
 - (6) It can be separated by physical means (evaporation, electrolysis, etc.).
 - (7) It is able to pass through filter paper without changing.
9.
 - (1) Temperature—solid solutes are more soluble in hot water than in cold. Gases are usually less soluble as the temperature increases.
 - (2) Pressure—little or no effect on solid or liquid solutes. With gases, the greater the pressure, the greater the solubility.
 - (3) Surface area—affects the rate of dissolution. The greater the area, the quicker a solute will dissolve.

- (4) Stirring—increases the rate a solute dissolves. This mainly affects solids.
- (5) Concentration—when the solute and solvent are first mixed, the rate of dissolving is at its maximum. As the concentration of the solution increases (increased solute), the rate of dissolving decreases greatly.

022

- 1. (1) b.
(2) d.
(3) c.
(4) a.
- 2. Inorganic compounds mostly use ionic bonds, which cause them to have high melting and boiling points; and organic compounds are held together by covalent bonds, which make organic compounds have low melting and boiling points).
- 3. Aliphatic and aromatic. Aliphatic hydrocarbons do not contain the benzene group, while aromatic hydrocarbons contain one or more of the benzene rings.

023

- 1. Analytical chemistry is concerned with the qualitative (what is it made of?) analysis and quantitative (how much is there?) analysis of the elements in a compound. Biochemistry is the chemistry of living organisms and their vital processes.
- 2. Simple carbohydrates are created by chlorophyll-containing plants through photosynthesis. Animals are incapable of creating their own carbohydrates, so they must get them by eating plants.
- 3. Sugars, starches, and cellulose.
- 4. (1) A *monosaccharide* is a carbohydrate that cannot be hydrolyzed (broken down) into a simpler carbohydrate unit.
(2) A *disaccharide* is a carbohydrate that can be hydrolyzed into two monosaccharides.
(3) *Oligosaccharides* are carbohydrates made up of three to 10 monosaccharides.
(4) *Polysaccharides* are also made up monosaccharides linked together, but these may number into the thousands.
- 5. Lipids.
- 6. Fats are glycerides, which are usually solid at room temperature, while oils are liquids at room temperature. Fats and oils are obtained from natural sources. As a general rule, fats come from animal sources, while oils come from vegetable sources.
- 7. Phospholipids, glycolipids, and steroids are types of lipids. *Phospholipids* are found in all animal and vegetable cells and are abundant in the brain, spinal cord, and liver. *Glycolipids*, also known as *cerebrosides*, are found primarily in the brain (these make up 7% of the dry weight of the brain) and at nerve synapses. *Steroids* are important to the body's chemistry because this group also includes many hormones.
- 8. Proteins.
- 9. Any three of the following:
 - (1) Structure: Proteins are the main constituents of bone, skin, hair, and nails.
 - (2) Catalysis: Just about all reactions that take place within the body are catalyzed by proteins called enzymes.
 - (3) Movement: Every time you move a muscle (scratch, blink, run, etc.), you contract or expand your muscles.
 - (4) Transport: Some proteins transport molecules across cell membranes, while others such as hemoglobin, carry oxygen from the lungs to the tissues and carbon dioxide from the tissues to the lungs.
 - (5) Hormones: Many hormones are proteins—insulin, epinephrine, and human growth hormone, just to name a few.

- (6) Protection: When an antigen (an outside protein) invades the body, the body makes its own protein (called an antibody) to counteract the foreign protein. Blood clotting is another protective function carried about by a protein (called fibrinogen).
- (7) Storage: Some proteins are used to store materials. In the liver, a protein known as ferritin stores iron.
- 10. Proteins are linear chains of amino acids. While organic chemists are capable of creating thousands of amino acids, only 20 make up all the various proteins in the body.
- 11. Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). Only DNA carries the hereditary information. This information tells the cell which proteins to manufacture.

024

- 1. Pound, gallon, and mile.
- 2. Each prefix designates a factor that must be applied to the primary unit. By combining the prefix and the primary unit, you may produce a larger or smaller unit of the property being measured.
- 3. In instances where the lowercase letter “l” may be confused with the number “1.”
- 4. SI is the abbreviation for the *Système Internationale d’Units* (or in English, the “International System of Units”), a system of measurement adopted by the international scientific community in 1960. It is based on the metric system and uses some metric units.
- 5. Basic properties refer to what is being measured and the base unit is the name given to the unit of measure for that property. Mass—kilogram; length—meter; time—second; catalytic amount—katal; and amount of substance—mole.
- 6. In SI, derived units describe properties other than the base units. Derived units are created by mathematically combining two or more base units. An example of a derived unit is volume, which is length in three dimensions—length \times length \times length.
- 7. Be sure to look at how your values are reported. If there is a change in reporting units, notify lab staff and providers of the change. Always include reference ranges to aid providers in basing decisions on numbering systems they are unfamiliar with.
- 8. A measured number, one in which the number of digits are known with certainty.
- 9. By reporting out a value with more significant figures than the equipment calls for, the technician has implied a precision in testing that does not exist.
- 10. The zeros in 10.02 are significant because they fall between two nonzero digits. The zeros in 3.00 are significant because they are to the right of a nonzero digit and are to the right of a decimal point to indicate the precision of the number. The zeros in 0.02 are not considered significant because they are to the right of the decimal and do not possess an actual value themselves, and they do not have a significant digit to their left.

Do the unit review exercises before going to the next unit.

Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter.

- 45. (019) A subatomic particle with a positive charge of one (+1) and a mass of one atomic mass unit is known as
 - a. an electron.
 - b. a particle.
 - c. a neutron.
 - d. a proton.

46. (019) What is the *maximum* number of electrons the third energy shell of an atom may contain?
- 2.
 - 8.
 - 18.
 - 32.
47. (019) Isotopes are atoms of the same element with the same atomic number but *different atomic masses*. This is because
- isotopes weigh more due to attached radioactive particles.
 - isotopes possess a different number of neutrons.
 - isotopes possess hydrated atoms.
 - isotopes weigh less.
48. (019) Although atomic mass is expressed as AMU, atomic weight is expressed as
- milliliters.
 - pounds.
 - AWUs.
 - grams.
49. (020) A molecule of a monatomic element has how many atoms in each of its molecules?
- 1.
 - 3.
 - 10.
 - 13.
50. (020) O_3 is an example of
- respiratory by-products.
 - a monatomic molecule.
 - a triatomic molecule.
 - chemical exhaust.
51. (020) Substances that are made up of two or more elements, chemically united in definite proportions by weight, are known as
- electrical charged particles.
 - bound material.
 - compounds.
 - mixtures.
52. (020) Compounds are formed from elements by bonding when
- an atom fills its valence shell.
 - molecules collide at high speed.
 - they are separated by a physical means.
 - they are exposed to low temperatures freeze.
53. (020) The statement, "Atoms always combine in such a way as to complete their valence shells," *best* describes the rule of
- eight (octet rule).
 - outside electrons.
 - bound compounds.
 - chemical neutrality.

54. (020) A symbol or group of symbols, with proper subscripts, representing one molecule of an element or compound is known as a
- scientific nomenclature.
 - chemical by-product.
 - chemical formula.
 - scientific title.
55. (021) When acids and bases react in a reaction called neutralization, what substance other than water is formed?
- Gas.
 - Salt.
 - Rust.
 - Oxide.
56. (021) Sodium and potassium salts are important for which body function?
- The acid-base balance.
 - For use by the thyroid gland.
 - The formation of hemoglobin.
 - For growth of bones and teeth.
57. (022) What type of chemistry deals with virtually all carbon-based compounds?
- Organic.
 - Inorganic.
 - Analytical.
 - Biological.
58. (022) Made up solely of carbon and hydrogen, which compounds form the basis of *all* organic compounds?
- Bases.
 - Acids.
 - Hydrocarbons.
 - Ionic solutions.
59. (022) Molecules that react the same under similar conditions or circumstances are said to belong to the same
- functional group.
 - chemical class.
 - periodic chart.
 - molar table.
60. (023) What type of chemistry investigates what a compound is made up of and how much of a substance it contains?
- Analytical chemistry.
 - Molecular chemistry.
 - General chemistry.
 - Biochemistry.
61. (023) What type of chemistry looks at an organism's growth, digestion, respiration, metabolism, and reproduction?
- Inorganic chemistry.
 - Analytical chemistry.
 - Pathological chemistry.
 - Physiological chemistry.

62. (023) Carbohydrates exist as cellulose, sugars, and
- fatty acids.
 - starches.
 - proteins.
 - lipids.
63. (023) Which of the following is *not* a function of proteins in the body?
- Proteins store iron in the liver.
 - Proteins catalyze reactions in the form of enzymes.
 - Proteins transport molecules across cell membranes.
 - Proteins convert brain impulses to electrical messages.
64. (023) Proteins serve to protect the body in which of the following manners?
- By making up muscle mass.
 - By functioning as hormones such as insulin.
 - By being the main constituent of hair and nails.
 - By forming antibodies against foreign proteins and blood-clotting functions.
65. (023) Protein synthesis is controlled by
- amino acids.
 - nucleic acids.
 - trilipoacidic acids.
 - phospholipemic acids.
66. (024) The measurement system based on combining a prefix and primary unit to produce larger or smaller units of a property is the
- scientific notation system.
 - English system.
 - metric system.
 - RDR system.
67. (024) While the metric system is based around primary units, the SI is based upon
- Arabic numbers.
 - basic properties.
 - French computations.
 - scientific mathematical computations.
68. (024) In the SI, there are basic properties and derived units. Which of the following is an example of a derived unit?
- Electrical current.
 - Length and time.
 - Volume.
 - Mass.
69. (024) A measured number, one in which the number of digits are known with certainty, is called a
- whole number.
 - scientific figure.
 - decimal number.
 - significant figure.
70. (024) A technician may get into trouble with significant figures if he or she
- reports out a result exactly as printed by the instrument.
 - reports out a result exceeding the instrument's capability.
 - reports out a whole number dipstick result as a whole number.
 - only reports out the result displayed on the instrument display.

71. (024) In which number are *all* the zeros considered significant numbers: 0.023, 00.023, 200.003, or 000.0023?
- a. 0.023.
 - b. 00.023.
 - c. 200.003.
 - d. 000.0023.

Please read the unit menu for unit 6 and continue. ➔

Student Notes

Unit 6. Laboratory Instrumentation

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HUMANS always strive to make their lives easier. The ability to learn, adapt, and create are some of the things that set us apart from other animals. Primitive humans used stone tools to go about performing their daily tasks. By comparison, the tools we use today are more complex and we are constantly striving for improvements. This unit is designed to give you an understanding of the principles behind many of today’s automated chemistry systems. Although the technology used by laboratory instruments is constantly changing, many of the principles behind the technology have remained the same. As long as you have a good grasp of these basic principles, you will be able to adapt quickly to the many analyzers on the market now and those to arrive in the future.

6–1. Introduction to Chemistry Analyzers

Over the past 20 years, there have been great advancements in chemistry automation. Many instruments incorporate the latest in medical and computer technology. Technology has allowed manufacturers to create systems that are faster, more economical, more precise, and less labor-intensive. Despite these advances, however, it still comes down to the laboratory technician who has to make it all go. We have all heard of equipment that was so easy to run, “they could hire a monkey to push the buttons.” While anyone might be able to push a button, it takes a trained individual to troubleshoot, analyze, and evaluate the quality of results put out by a system.

025. History, terms, and light principles

As is the case with many things in life, a brief subject background and an understanding of key terms make understanding the subject much easier. Laboratory analyzers are no exception. In the past, you probably used equipment without much thought about what made it work. In learning the theories and applications, you will advance well beyond the “push-button monkey” mentality.

History

Before World War II, only a few simple laboratory procedures were performed. Most of these procedures were done in the doctor’s office. Equipment was minimal and normally consisted of a monocular microscope for looking at urine sediment and stained smears, a Bunsen burner for simple urine sugar and albumin testing, and a color chart for estimating hemoglobin concentration.

During the 1930s, the number of tests available increased and the laboratory became an accepted part of hospital services. New equipment (such as the hand-cranked centrifuge and the autoclave) and new testing procedures were developed. Reagents and standards for chemistry tests were created in-house, often using inaccurate balances and glassware. Chemistry procedures were colorimetric, and results were based on visually comparing the patient tube to the closest matching standard tube. To alleviate some of these problems, kits were developed to make testing preparations (and result reporting) more uniform.

The introduction of the Duboscq colorimeter began the search for ever-increasing precision and accuracy in laboratory testing. The Duboscq colorimeter contained scales, graduated in millimeters, to

compare the intensity of a test solution's color to the color intensity of a standard. This method provided one of the first means of precise measurement rather than simple visual standard matching.

Although the Duboscq colorimeter was a leap forward for the accurate testing of patient samples, it was still dependent on the interpretation of the technician. Not everyone could match colors equally (especially those with color-vision problems). The invention of the photoelectric cell corrected this flaw by removing personal judgment from the testing process. When a photoelectric cell is exposed to light, it produces a small electric current. The strength of the current is proportional to the intensity of the light passing through a testing solution and, thus, proportional to the light-absorbing analyte in the solution. As improvements were made to photosensitive devices and their ability to measure light accurately, so laboratory-testing methods improved. More information on the properties of light and its relation to testing follows later.

Instrumentation as we know it today began coming to the market in the 1950s. One of the stumbling blocks to these early automated methods was the interference of protein. When heated or chemically treated, the protein in plasma or serum samples would often coagulate and become opaque. Once opaque, the sample would not allow light to pass through it, making a photoelectric reading impossible. To visualize this problem, think of a raw egg. The egg white, uncooked, is clear and allows light to pass through it quite readily. Expose the egg white to heat (cook it), and it turns opaque, severely limiting your ability to see through it. Prior to the 1950s, testing required samples to have the protein removed (relates to the term "protein-free filtrate"). In addition to being time consuming and awkward, there was a great chance for technician error when making the protein-free filtrate.

The Technicon Corporation finally overcame the problem of protein interference in the late 1950s. By using semipermeable membranes, they were able to separate the analyte requiring testing from the interfering proteins. In 1957 they introduced the first practical automated testing system, the AutoAnalyzer.

As new technology is developed, it is often applied to laboratory instruments. Change from vacuum-tube technology to solid-state electronics has helped make laboratory instruments smaller, more sensitive, and cost-effective. Improvements in optical techniques, specialized plastics, radioactive tagging, and electrode design have also contributed to the analyzers available on the market today. As technology continues to change and improve, so will the instrumentation in the laboratory.

Types of analyzers

In order to fully understand the various types of automated instruments found in the laboratory, you need a basic understanding of the terms used to describe these analyzers. Each term describes a feature used by an analyzer.

Batch analyzers

Batch analyzers operate just as the name implies. These analyzers run the same test or group of tests on all the samples in a run. Batch analyzers are good if the patient testing profile is limited.

Random access analyzers

Random access analyzers allow the technician to decide which tests are to be run on a sample. This is done independently of all the other samples in the run. Random access analyzers provide more flexibility in patient testing, yet they require more of the operator's time because now each sample request must be input individually.

Continuous flow analyzers

Continuous flow analyzers pump reagents through the testing system continuously and introduce samples at regular intervals. Peristaltic pumps accomplish the pumping of reagents and samples through the system. In addition, the lines are continuously scrubbed by air bubbles moving through

the lines. These air bubbles are also used to separate one specimen from another. Continuous flow analyzers are usually used for batch testing, running the same tests on all samples.

Discrete analyzers

Discrete analyzers process each sample separately; each test occurs in its own reaction container. Discrete analyzers generally follow the same steps as manual testing with the exception being that the analyzer performs all the pipetting, mixing, incubating, and reading of the test solution.

Centrifugal force analyzers

As the name implies, these analyzers use centrifugal force to transfer and mix the reagents and samples. The reaction cuvette, which is located at the outside edge of the sample and reagent disk, is read by a photometric system while the disk is spinning with readings taken at each revolution.

Walkaway capability

When an instrument has walkaway capability, it means that the operator can program the instrument to run a series of tests and then leave the instrument to perform the procedures. The main advantage to walkaway capability is that the operator is free to perform other tasks while the instrument processes the tests.

Analyzer properties

A good analyzer has specific characteristics. Let's take a look at some.

Linearity

The linearity of an instrument is the reportable range for patient results without manipulating the sample (making a dilution). Verify instrument linearity periodically, at least annually as a minimum. The larger an instrument's linearity, the fewer dilutions an operator will have to make. This saves the operator preparation time and decreases the turnaround time of results.

Specificity

An instrument's specificity is its ability to measure only the analyte being tested. If an instrument has low specificity, it may measure interfering substances in the reaction and yield a false result. For this reason, you must always be aware of the limitations of your testing method and any interfering conditions (if any).

Sensitivity

The sensitivity of an instrument is the lowest value for a test method that can be reported accurately.

Accuracy

A method's accuracy is its ability to determine the actual value of an analyte.

Precision

Precision we define as "the reproducibility of an instrument." Remember that just because a test is reproducible, it may not necessarily be accurate. To illustrate this point, think of a drill team. If each member is performing precisely the same movements, but the members are all marching in different directions, their routine is off the mark. Testing results can be the same way; they may all be doing the same thing but be far off the mark (of their actual value).

Light principles

Light is a form of electromagnetic energy that travels in waves. The distance between the peaks of the waves we know as the *wavelength of light*. The wavelength of light determines the color of the light and whether it can be seen by the human eye or not. Each color within the spectrum is made of light of a particular wavelength. By combining all the colors (wavelengths) together, you get white light.

Sunlight (as long as it is unfiltered by clouds, dust, etc.) is considered white light because it contains all of the light wavelengths.

When white light, such as that from the sun, hits a prism, a rainbow or *spectrum* of colors is produced (fig. 6-1). When light hits a surface that causes it to diffract or bend, each color is seen separately. In the laboratory setting, the wavelengths you need to be concerned about are the ultraviolet, the visible, and the near infrared regions (fig. 6-2).

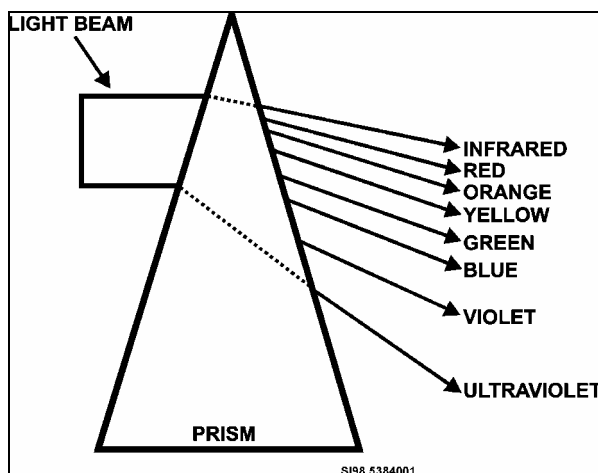


Figure 6-1. Refraction of light by a prism.

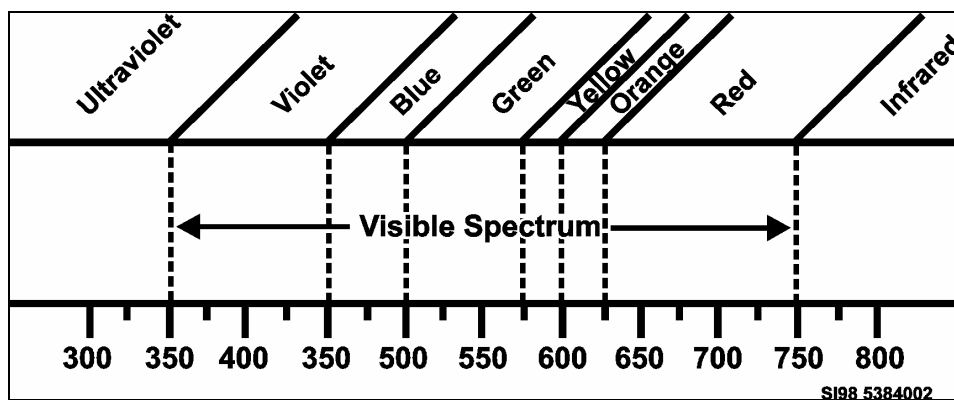


Figure 6-2. Wavelengths common to the laboratory.

Most solutions contain particles that absorb certain light wavelengths and transmit others. It is transmitted light that gives a solution color. For example, when you look at a red solution, it appears red because the particles in the solution have absorbed the wavelengths of all other colors except the red ones. These particles allow the red wavelengths to pass through (causing you to see the solution as a “red” one). The ability of a substance to allow light to pass through it we know as *transmission*. The light that does not travel through a substance is said to be *absorbed* by the substance.

The absorbance and transmittal of light are what makes up basic principles of many of the earliest laboratory analyzers such as spectrophotometers. Analytes are measured by creating a reaction between the substances to be measured and a reagent or chemical. When these substances and chemicals mix, a color is formed during the resulting reaction. If the amount of reagent is standardized, the amount of color produced in the reaction is dependent on the available amount of substance being measured. The intensity of a color seen is directly proportional to the concentration of the substance being tested. This concept is known as *Beer's law*.

To further illustrate Beer's law, if you saw a solution with a very intense color (let's use red for example), you could correctly assume that it had a high concentration of a substance that made it look red. As you decreased the amount of the substance making the solution red, the color intensity of the solution would decrease accordingly. Increasing a color-producing substance would also increase the amount of color seen. One of the key items to remember about Beer's law is that the depth of the solution where you take your reading must remain constant.

Errors in testing can occur when the depth or light path (the distance the beam of light must travel through a solution) fluctuates. *Lambert's law* is the one that is concerned with the depth of a solution. Simply stated, Lambert's law says that the absorbance of a solution increases linearly when you increase the light path. For example, the absorbance of a solution that is 4 cm is twice that of a solution that is only 2 cm deep. As you can see from Lambert's law, errors in your cuvette, such as air bubbles, may cause a significant error in your testing so consistency is key. You may, on occasion, see Beer's law and Lambert's law combined and expressed as "Beer-Lambert's law." This is because the two laws are closely related and often work hand in hand with each other.

026. Instrument maintenance and troubleshooting

Laboratory analyzers are the tools you use for your day-to-day work. If used improperly or not maintained, the analyzer will not perform as required. An improperly maintained analyzer usually breaks down at the point when you need it the most, proving one of Murphy's laws, "If anything can go wrong, it will." If you follow the scheduled maintenance procedures in the manual for your specific equipment, you can increase your standing as a steady performer with the staff and avoid having to make embarrassing explanations about "what went wrong." In this lesson, you will learn some of the general guidelines to keeping your equipment running smoothly and where to look when those pesky, occasional problems develop. The following procedures in maintenance, QC, and routine documentation play a large part in ensuring accreditation of your laboratory as well.

Routine care

After you settle into a laboratory, it is easy to establish a daily pattern. Patterns or the "same old daily grind" can be a good thing as long as your pattern is properly established. Normally, the QC procedures you perform daily have your equipment's routine maintenance procedures built in.

As part of your QC program and routine maintenance, there are certain functions that you must perform daily, weekly, monthly, and yearly. When you are assigned to use equipment for the first time, the best thing you can do is read the manufacturer's manual. Often in the laboratory, one person shows the next person how "we do it here." While there is nothing wrong with that type of in-house training, there is the chance for miscommunication or diluted training (because over the course of time the key points may get "diluted" or forgotten and not passed on). By reviewing the manual yourself, you ensure that you know the "key" points to running the instrument equipment. Just because someone else had an established program for a particular piece of equipment, that person's program may not be technically correct. By reading the procedure manual, you verify that programs are technically correct. Reading the manual allows you to trust yourself. Remember, if you have to explain to health-care providers why they cannot have a result or tell an inspector why your records are incomplete, they will not care what the person before you did. Learning all you can about the equipment you work with makes you the subject expert, helps you keep your equipment running smoothly, and increases your professional standing among your peers and superiors.

There are several items that must be performed routinely on all types of equipment. First and foremost, equipment must be clean and in good condition. If you allow chemicals and solvents to spill and sit on the equipment, you are asking for trouble. In addition to possible health concerns (sample and reagent spills are great disease-breeding areas), spills can corrode equipment, create films on optical windows (affecting sample readings), or otherwise create the potential for problems. Next, check all your reagents prior to your testing run. A time-saving analyzer does not do you any good if

you have to repeat a run because a reagent well went dry. Check the temperature of your equipment as many reactions are driven by it. If you create a systematic method of performance, you can be sure that required tasks are completed and performed correctly.

Following your daily equipment checks (usually established in your OI), it is a good idea to review the calibration of your instrument. Calibration “locks in” a value for a standard on an instrument. If equipment is improperly calibrated or affected by some other cause (lamp burning out, bad timer, etc.), analyzer precision and accuracy may be affected. Be sure to record all instrument calibrations as part of your routine maintenance. Just because your results “look right,” do not assume that the calibration is fine. In addition to calibration, reference controls play a big part in your regular checks. QC programs and equipment maintenance work hand in hand and depend greatly on each other. Look at each aspect of your equipment and quality control individually, even if the “big picture” looks OK. By looking at the smaller parts of the big picture, you can detect little problems and correct them before they reach crisis proportions.

Method correlation

Whenever your lab receives new instruments or updates a method, you also need to perform a method correlation. Keep in mind also that when new equipment arrives in the laboratory, the first step is to perform a validation prior to reporting patient results (validation we covered earlier). Method correlation ensures that different instruments or procedures will yield similar results if all things are equal. Most often, we do this correlation by running the same samples on the old and new instruments or methods. By comparing the results, you can compare the known (your old instrument) to the unknown (your new instrument) and establish the adequacy of your new method. In some instances, there will be a wide variation in the range of results for different methods. This does not necessarily mean either method is incorrect (although you may want to verify that each analyzer is running correctly). When a difference occurs, you may need to establish a new set of reference ranges for the new instrument or method. In addition to establishing this new range, be sure to educate the staff (let the doctors and nurses know about the shift in reference ranges) through in-services or other methods. If you provide results using varying methods (say you use one instrument in a “STAT lab” and another in the “routine lab”), be sure your results are accompanied by the reference range for the test method or instrument you used to run the test.

Remember, people are typically resistant to change. Some health-care providers prefer getting the results using the reference ranges to which they are accustomed. By communicating the changes and being able to prove your new method through correlation, you reduce the resistance to change and achieve the physician’s trust in you and your results, which in the end is better for the patient.

Equipment repair

When it comes to equipment repair, remember first and foremost—safety, safety, safety. Never put your hands (or any other parts of your body) into a piece of equipment that is working its way through a cycle. Be sure to remove rings, watches, and bracelets before working on electrical equipment and to secure or remove ties, loose clothing, or long hair when working on chain- or gear-driven items. Never, ever attempt to override a safety feature on a piece of equipment. Now you may be thinking, “Who would do that?” You might be surprised. That moment of haste can cause waste, either through personal injury or equipment damage. The bottom line is this; it’s just not worth taking the chance.

Another aspect of equipment repair is knowing your limits. Most folks can easily follow the directions in an owner’s manual for changing bulbs or tubing, but changing a drive train or digital readout may be another matter all together. As you become more experienced and familiar with a piece of equipment, you learn to do more intense maintenance yourself. The key is not to perform any repairs that exceed your qualifications. If in doubt, refer the problem to the folks who are trained to do the job. In many cases, this is required in order to keep the warranty intact. There is nothing wrong with calling biomedical equipment repair or the factory service representative. By calling in those

trained to do the job, you will probably save yourself a lot of time and effort as well as avoid making a bad situation worse.

Regardless of who repairs a piece of equipment, ensure that anything done to the equipment is documented. Just about every laboratory facility has its own method of recording equipment repairs. Regardless of how your facility documents repairs, just make sure the documentation occurs. In addition to being part of the overall QC program, documentation can have other impacts. If you are a night tech and suddenly a piece of equipment is not operating properly, equipment records may prove to save time and allow for correction. By reviewing the equipment record, you may find that a particular problem has happened before and how it was corrected so that you can apply the solution in your case. Having access to this information may allow you to fix the problem on the spot and continue with testing. Good equipment records are also essential when it comes to upgrading equipment. As a general rule, once you have spent about two-thirds of the original purchase price on repairs, it is time to replace a piece of equipment. Good documentation of problems and the costs of repairs will support requests for new analyzers. During these days of cost-control measures, every little bit of information regarding costs can help to push your request package through for approval.

Troubleshooting

As odd as it may sound, the first step in troubleshooting is being able to recognize that a problem exists. This may sound like a “no-brainer” statement, but in fact many analyzers may still produce a result (inaccurate as it may be) while it is malfunctioning. Not all instruments just stop running when there is a malfunction. This is because the problem may be intermittent or may slowly develop over time. Examples of these types of problems include, but are not limited to, running out of one or more reagents, a clogged sample line, and a light source that might be flaring or dimming just before it burns out.

In many cases, instrument malfunctions begin as subtle problems. By being familiar with the equipment you work with, you learn the analyzer’s “personality” (machines you may find, like people, have their own little quirks and can become temperamental under certain conditions). Your perception of your analyzer allows you to make the distinction between normal and abnormal operations. Technicians who are poorly trained or not in tune with the instrument typically miss these subtle hints that indicate a problem. Unfortunately, when these oversights occur, potentially erroneous results are reported. Earlier, we discussed the “a monkey could do this” mentality. Troubleshooting equipment is a perfect example of why laboratory medicine will always require a “human factor,” because human interpretation can be all the difference in such cases.

Once you determine a problem may exist, the next task you face is isolating or determining the problem. Often, this step is nothing more than matching cause and effect. Most analyzer manuals contain an index for troubleshooting common problems as well as the steps for common solutions. Over the course of time, your confidence level for troubleshooting an analyzer will increase as you become more familiar and experienced with it. Always attempt to be systematic in your approach to troubleshooting, working from the simple (is it plugged in) to the more complex (replacement of the motherboard). Simple things like the housekeeping staff unplugging an analyzer so they can wax behind it (but forgetting to plug it back in) can create a feeling of instant panic.

Always remember that, as an instrument operator, you always have two options. You may correct a problem yourself if it falls within your scope of expertise, or you may decide to refer out the problem to biomedical maintenance or a company service representative. Always choose the appropriate avenue for remedy.

On a final note, there is one more piece of advice about troubleshooting that you need to know. This piece of advice is often overlooked more than any other factor when trying to determine a problem. “What is that advice?” you may wonder. It is simply this, “When in doubt, read the instructions!”

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

025. History, terms, and light principles

1. What was one of the stumbling blocks to automated laboratory testing as we know it? Why?
2. Describe how the first practical automated testing system overcame the problems of protein interference.
3. Match the analyzer characteristic in column A with the appropriate analyzer name in column B. Each item in column B may be used once, more than once, or not at all.

Column A

- ____ (1) Runs the same test on all the samples in a run.
- ____ (2) Allows the technician to decide which tests are run on a sample.
- ____ (3) Pumps reagents through the system continuously.
- ____ (4) Processes each sample separately and in its own reaction container.
- ____ (5) Uses centrifugal force to transfer and mix reagents and samples.

Column B

- a. Random access analyzer.
- b. Continuous flow analyzer.
- c. Batch analyzer.
- d. Centrifugal force analyzer.
- e. Discrete analyzer.

4. Match the statement in column A with the performance characteristic in column B. Each item in column B may be used once, more than once, or not at all.

Column A

- ____ (1) Operator is free to perform other tasks while the instrument processes the tests.
- ____ (2) The reportable range for patient results without sample manipulation.
- ____ (3) The ability to only measure the analyte being tested.
- ____ (4) The lowest value for a test that can be reported accurately.
- ____ (5) The ability to determine the actual value of an analyte.
- ____ (6) The reproducibility of an instrument.

Column B

- a. Linearity.
- b. Specificity.
- c. Accuracy.
- d. Sensitivity.
- e. Precision.
- f. Walkaway capability.

5. Explain the difference between accuracy and precision.
6. What does the wavelength of light determine?
7. What wavelengths are you concerned with in the clinical laboratory setting?
8. Explain why a “red” solution appears red.

9. Explain the concept of Beer's law.
10. Explain the concept of Lambert's law.

026. Instrument maintenance and troubleshooting

1. Equipment maintenance procedures are normally built into what daily program?
2. When you are tasked to use a piece of equipment you have never used before, why must you review the manufacturer's manual?
3. Why must you make sure your equipment stays clean?
4. Why must you look at each aspect of equipment maintenance and quality control separately?
5. What does "method correlation" ensure?
6. How do you do method correlation? What do you do if there is a difference between the old and new methods?
7. If an equipment problem is beyond your expertise, to whom do you refer the problem?
8. In addition to impacting QC programs, why do you document equipment maintenance?
9. Why is it important for you to be familiar with the equipment you are using?
10. What sequence do you follow when troubleshooting equipment?

6-2. Chemistry Analyzer Principles

One of the wonders of living in these “modern times” is the amount of change going on around you. Improvements in technology are happening so quickly that the model of equipment you buy today is outdated practically by the time you unbox it in your lab. For that reason, we **do not** discuss specific brands or makes of laboratory analyzers, but rather we introduce you to instruments based on their general titles and operating principles.

027. Analyzers using electrochemistry

Dynamic changes regarding the advancements in laboratory analyzers occurred in the 1980s. Flame photometric and colorimetric systems were largely replaced by electrochemical analyzers. In fact, electrochemical analyzers are now found in just about every clinical chemistry laboratory.

Principles, components, and limitations of electrochemical analyzers

Electrochemical analyzers were the answer to a search for safer, accurate, less cumbersome, and more precise testing systems. Electrolyte and lithium determinations were performed on flame photometers, a method that was labor intensive and dangerous. By implementing electrochemical techniques in testing, equipment manufacturers were able to incorporate the testing of various analytes all into one machine. Laboratory managers now only needed one machine and one technician to do the job that previously required many pieces of equipment and many technicians.

We use the term “electrochemistry” to describe the process of chemical energy being converted to electrical current in a galvanic cell (“galvanic”—a French term meaning chemically produced electricity). Electrochemical reactions are characterized by oxidation (a loss of electrons) at the positive pole (anode) and a gain of electrons at the negative pole (cathode). The galvanic (or electrochemical) cell is made up of two parts; each part is called a *half-cell*. The half-cells are filled with a metal in a solution (in the form of a metal salt). Electrochemistry involves measuring the current or voltage generated due to the activity of specific ions in the electrochemical cell. The activity of the ionic form of an analyte is directly proportional to its concentration.

Electrochemical methods are used in the clinical laboratory to measure ions, drugs, hormones, metals, and gases. These methods are easily applied to items in high concentrations such as electrolytes in the blood, as well as those in low concentrations such as heavy metals or drug metabolites in the urine. A key point in favor of electrochemical methods is that testing can be performed on very small sample amounts. There are several general electrochemical techniques used in clinical chemistry today; most we cover briefly here. Of the different electrochemical methods, the potentiometric method is the one that probably has the most impact on chemistry testing.

Potentiometric method

Potentiometry measures the comparison of the potential of one electrode to the potential of a second electrode. The measurement for this method is based on the potential difference between two electrodes immersed in a solution under zero-current conditions. The differing voltage is usually displayed on a pH or voltage meter.

Just about all conductors of electricity are metals or electrolytes with the current being carried by either electrons or ions. Whenever there is an interface between metal and the ions of that metal in a solution, an electrical potential is produced. Nonmetallic elements (such as hydrogen) also have electrode potentials.

To measure electrode potential, we measure one voltage source against the other. This is where the half-cells come into play:

- Reference electrode: half-cell that maintains constant voltage. We know the potential of this electrode as constant potential.

- Indicator electrode: half-cell that contains an unknown solution that causes varying voltage. We take the measurement from this electrode. This electrode is sensitive to the concentration of the analyte being measured.

Ion selective electrodes (ISE) are examples of indicator electrodes. By knowing the potential differences in each half-cell and the concentration of the reference electrode, you can readily calculate the concentration of your test solution (fig. 6-3).

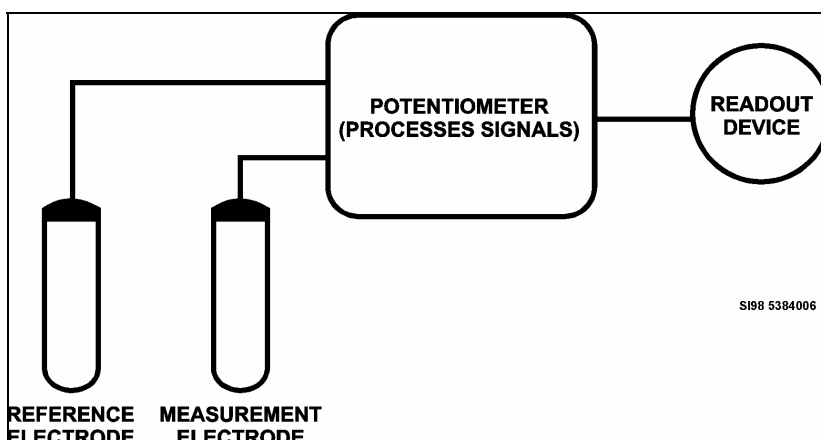


Figure 6-3. Basic process of electrode systems.

Coulometric method

The most common application for coulometry is in determining chloride ion concentration in serum, plasma, urine, or other body fluids. If a constant current is used to create a titrating agent, the time it takes to create that titrant is related to the amount of analyte in the sample. Using chloride analysis as an example, let's examine this principle further.

By passing a carefully controlled current between two silver electrodes in an ionic solution, silver ions will be released by one of the electrodes. If chloride ions are in the solution, these will combine with the released silver ions to produce silver chloride (an insoluble substance). A silver-detecting electrode and a reference electrode are also part of the system; their function is to sense the excess silver ions in the solution once the chloride ions are used up. When the excess silver ions are detected, the current to the silver-releasing electrode is discontinued. The amount of electricity used is directly proportional to the amount of substance produced or consumed by the electrodes.

Although primarily used for chloride testing, coulometric methods can also be used to perform acid-base titrations. In an acid-base application, we use a platinum generator electrode.

Anodic stripping voltametry method

In anodic stripping voltametry, the working electrode normally is a mercury-coated graphite rod. When a negative potential is applied to the electrode, the metal ions in the sample plate the electrode. The plating is allowed to proceed for a fixed amount of time (30 seconds to 30 minutes, depending on the concentration of the analyte being tested). After plating, the deposited metal ions are removed by applying an increasingly positive potential. As each ion returns to the solution, a sharp current peak occurs at a potential level that is characteristic for each metal. The peak height is directly proportional to the concentration of the analyte. Comparing unknown peaks to peaks of known standards derives quantification of unknown samples. We most commonly use the anodic stripping voltametric technique to quantify heavy metals (such as lead and copper) in blood and urine specimens.

Polarography method

We most commonly use polarographic equipment in analytical chemistry and not clinical chemistry except for measuring the partial pressure of oxygen (pO_2).

028. Analyzers using separation techniques

Until now, we have learned the principles behind laboratory analyzers using the light or electrical characteristics of a substance in order to determine a quantity. In most of the cases studied, each analyte was quantified on its own. Here, we cover analyzers that separate samples into various analytes. The one sample then yields the results of several analytes within the specimen being studied. There are two separation techniques that you must be familiar with: chromatography and electrophoresis.

Principles, components, and limitations of chromatography

Chromatography is the term we use to describe the separation of substances in a common solvent so that we can identify each component individually. The basic process of chromatography we can characterize as passing a solvent through a supporting (or filtering) medium. This medium allows some portions of the solvent to proceed through faster than others, thus separating the solvent into different components. Once these components are separated, they are passed through a detector where their amounts may be quantified. The filtering medium allows some components to proceed faster than others.

The chromatography process we can divide into two phases—a mobile phase and a stationary phase. The mobile phase, as the name implies, describes the solvent moving along the process. The stationary phase describes a compound “hanging up” or becoming stuck when it comes in contact with the supporting medium column. Chromatography techniques are named based on the type of mobile phase they use. If the mobile phase is liquid, the method is called *liquid chromatography (LC)*, and it is called *gas chromatography (GC)* if gas is used for the mobile phase.

Once the various components are separated and passed through a detector, the results are normally charted onto a graph. As each separate component passes through the detector, the recorder plots the detector response as a peak against a time line. Since each component comes off at different times, your graph will be a series of peaks and valleys visualizing the makeup of the sample being tested. We use the size and amount of time a peak is displayed to help calculate the amount of a component present. The mathematical formulas required to do these computations would require going into a depth far more complex than what is required for this lesson.

Gas chromatography

In the GC method, the substances being analyzed are in a gaseous state. The solvent that carries the material through the filtering column is a stream of inert gas (usually helium or nitrogen). The filtering columns contain an inert material such as crushed firebrick. The columns are usually small-diameter tubing several feet in length (coiled to save space) that contain crushed firebrick or similar inert material. As the carrier gas and analytes exit the column, they are analyzed and results are recorded on a strip chart. Unless the substance being measured is a gas (e.g., oxygen, carbon monoxide, etc.), all parts of the chromatograph need to be heated so the material being analyzed is kept in a gaseous state (fig. 6-4). A disadvantage of GC is that we can only use it to measure compounds that are naturally volatile or that can be converted to a volatile compound. This factor limits testing using GC methods to only 10% to 20% of all known compounds.

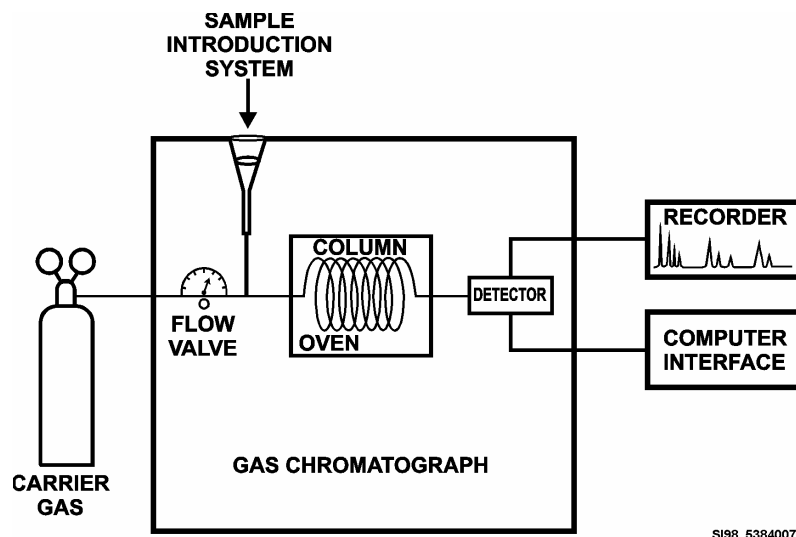


Figure 6-4. Gas chromatography system.

Liquid chromatography

An alternative to overcome drawbacks of GC is LC (formerly “column chromatography”). In LC, the mobile phase uses a liquid to act as a carrier. This method’s stationary phase uses ion-exchange resin, alumina, or silica gel in a column with a device at the bottom of the column to keep in the filtering material but allow the liquid to pass through. The testing mixture usually is added as a slurry that is allowed to pass through the column by gravity, or in some cases, with the aid of applied suction or air pressure. As the solvent flows through the column, the substances being separated move down the column at different rates of speed, depending on how they are adsorbed by the column material.

There are two advantages of LC over GC. First, we can use LC to separate any compound that is soluble in a liquid phase, and second, the use of a liquid mobile phase can be performed at lower temperatures (essential when trying to separate thermolabile compounds). LC methods usually are less efficient and produce much broader peaks than GC methods. Most commonly, we use LC techniques for sample purification and the removal of interfering substances before testing with other methods.

Other methods

There are, of course, other methods. Let’s discuss a few.

High-performance liquid chromatography

A more efficient method of LC is high-performance liquid chromatography (HPLC). In HPLC, the support medium in the column is much smaller and more uniform than that used in “regular” LC. By using the smaller support medium, the sample peaks are much narrower than those seen in LC. To pass the sample through the smaller column medium, we must use special pumps. These pumps create high pressure, which is required to push the mobile phase through the densely packed column material.

Thin-layer and paper chromatography

Although most gas or liquid chromatography is done using coiled or straight columns (gas uses coiled and liquid uses straight), there are some methods that have the filtering material in a flat bed. When flat beds are used, we call the technique *thin-layer chromatography* (TLC). We use TLC methods most commonly when screening a large number of samples for known substances such as amino acids

or drugs. *Paper chromatography* is a variation that uses paper as a flatbed material for the stationary phase.

Following separation, flatbed methods usually are stained or dipped into a reagent that will yield a color reaction. The separated, distinct spots or areas correspond to the individual compounds. The size of the spot or intensity of the color normally is proportional to the amount of the substance present. These colors we can compare to spots obtained with known amounts of standards run similarly.

GC/mass spectrometry

Sir J. J. Thomson performed the first mass spectrometry (MS) in 1912. Improvements led to the first commercially available models in the 1940s. Since 1980, advances in electronics and computers brought about drastic changes to this type of analyzer, making them simpler and more affordable for many labs.

By combining GC and MS methods together, one of the most powerful analytical methods available is created. GC/MS has an unparalleled specificity and sensitivity. In the clinical setting, we usually use GC/MS for the analysis of drugs and trace analytes. Since GC/MS is so precise, the National Institute of Standards and Technology (NIST) has declared it a “definitive method” for qualifying standard reference materials.

In GC/MS analyzers, the sample is first converted into a gaseous state. This gaseous sample is then placed in an ionizing chamber where an electron beam bombards the molecules. As the beam strikes the molecules, the molecule may eject one of its electrons. If this happens, the molecule becomes positively charged (ionized). Positive ions are attracted to a negatively charged plate and then directed to an acceleration tube in a mass analyzer. The mass analyzer is a magnetic field; when the sample ions interact with the magnetic field, their travel path is bent. The degree of ion deflection depends on the mass-to-charge ratio of the sample ions. In the mass analyzer, the positive ions are separated according to their mass-to-charge ratio. This results in a spectrum of sample masses (as opposed to a spectrum of light in a spectrophotometer). The mass spectrum is scanned by a detector that determines the ionic characteristics of each component of the sample and the amount of each present.

Analyzers using electrophoresis

Electrophoresis is yet another technique we use to separate or fractionate a sample to determine its makeup. This process differs from chromatography in that it uses electrical current for separation rather than mechanical means. Electrophoresis we define as “the migration of charged particles in a liquid medium when subjected to an electrical charge.” Electrophoresis is especially well suited for testing macromolecular substances such as proteins and lipids. It is also used routinely to test hemoglobins, enzymes, amino acids, and other substances of medical and biological importance.

Principles of electrophoresis

The principle of electrophoresis began in the 1860s when a German investigator, Heinrich I. Quincke, demonstrated a relationship between the speed of particle migration and electric potential. He also noted that there was a relationship between the speed of migration and the pH of the suspending medium. Several advances in this principle ensued throughout the years to where we are today with quantification methods.

Electrophoresis separates particles using electricity. In electric circuits, electrical current is a flow of electrons through the circuit. As you increase the voltage, you increase the electron flow. With that in mind, think of electrophoresis as a circuit running through water with dissolved salts (rather than through metal wire). Instead of looking at electrons, electrophoresis looks at the flow of charged ions in a solution (this process is known as *conductivity*).

When salts are dissolved in water, they form ions. Using sodium chloride as an example, sodium ions form (each with a positive charge) as well as chloride ions (each with a negative charge). In water, all ions become hydrated; this means that they cluster with water molecules. Ions with the same charge may move through the water at different rates. This is because some may be carrying more molecules of water than others.

In electrophoresis, voltage is applied to a solution by placing electrodes into the solution. Electrophoresis electrodes normally are made of platinum because it is a good conductor and chemically inert. One electrode is attached to a positive voltage source (*anode*); it then attracts negatively charged ions (*anions*). The other electrode we connect to a negatively charged voltage source (*cathode*); it then attracts the positively charged ions (*cations*).

Also of great importance to the electrophoresis process is the pH of the solution. Proteins may be cationic or anionic, depending on the solution pH. When you place a mixture of proteins into a solution at a given pH and apply voltage, the proteins with a positive charge will move toward the cathode while those with a negative charge will move toward the anode. Those proteins without any charge at all will not move. By changing the pH of your solution, you may also change the ionic characteristics of the proteins in the mixture. By changing these characteristics, you may change not only the rate in which they move but also the direction of their movement. It is for this reason that solutions in electrophoresis testing are always buffered to maintain pH.

Supporting medium

As a general rule, the sample you are trying to separate is heavier (or more dense) than your electrophoretic solution. For this reason, use a supporting medium that keeps the sample and separated fractions from falling through the solution and remixing. When the sample is exposed to a charge, the ions in the sample will move along the support medium. Like ions will travel like distances along the medium, revealing an electrophoretic pattern. An important consideration in determining a support medium is whether or not a given medium will bind or adsorb what you are trying to separate. Early electrophoresis techniques used filter paper as a supporting medium. Unfortunately, proteins had a tendency to adhere to the fibers in the filter paper, thus leaving a less than clear-cut separation pattern. Currently, agar gels, membranes, and cellulose acetate strips are used in place of paper. These mediums provide a more uniform migration as well as faster, sharper separation.

Densitometers

In order to semiquantify the fractions on the supporting medium, the plate or strip is read on a densitometer. A densitometer is a modified spectrophotometer and takes absorbance measurements. A beam of monochromatic light is shined through the supporting medium (this beam we call a “reference” beam), and another is passed through the electrophoretic pattern (the “sample” beam). The two signals, reference and sample, are then passed through a detector and amplified. The difference between the amplified reference signal and the amplified sample signal is then used to drive a recorder that traces the pattern observed. This pattern represents the amount of material deposited onto the support medium during its migration.

Like all spectrophotometers, densitometers have a light source and a method of making wavelength selections. The use of red lasers as a light source in densitometers is becoming more common. By combining technological advances in detectors and the use of laser beams, the analyzer can record many fine details in the stained gel. Interpretations of electrophoresis patterns we can then do by comparing a patient pattern to a “normal” or “control” pattern.

029. Analyzers using immunoassay and other techniques

Immunoassay methods are currently used to detect a wide range of clinically significant substances that are difficult to detect using some of the methods we have studied previously. Typically, immunoassays use an antibody as a reagent to detect a specific antigen (or chemical substance) of

interest. Detailed information about antibody/antigen reactions we cover later. In this lesson, we explore the use of immunoassay techniques as well as a few other miscellaneous techniques in laboratory analyzers.

General immunoassay principles, components, and limitations

We use immunoassays to measure things such as drugs (therapeutic and abuse), hormones, tumor markers, proteins, vitamins, and other compounds that may be present in minute quantities. In most cases, the so-called “traditional” testing methods are not sensitive enough and are inadequate to use for analyte detection because they lack specificity. Immunoassay, however, uses a specific reaction between antibodies and antigens. Because antibodies and antigens are specific for one another, you may test for either by using the other as a search vehicle.

As you may recall from previous training, antibodies and antigens bind or fit together like pieces of a puzzle. These pieces only join at a specific receptor site with few exceptions. There are a few analytes that react with antibodies in vitro (in the test tube) that are not antigenic in vivo (in the body). These analytes we know as *haptens*. To include these exceptions to the immunoassay testing process, we use the term *ligand* to represent the analyte being measured.

When we look at the immunoassay process, an antigen (ligand) or antibody must be chemically bonded or tagged with some sort of tracer. The tracer has one of a few options—it can remain free in solution or it may bind to an antigen-antibody/binding protein complex. Early immunoassay procedures used radioactive isotopes as a tracer, but enzymes, fluorescent molecules, and chemiluminescent compounds are more commonly used today. Reactions are read using photometric methods to determine the analyte of interest. There are three primary methods of immunoassay: radioimmunoassay (RIA), enzyme immunoassay (EIA), and fluorescent immunoassay (FIA).

RIA

Radioimmunoassay, as its name implies, uses a radioactive antigen to bind to the sites on the antibody molecule. RIA methods often are used for measuring hormones with a low circulatory concentration in the blood. RIA may also be used to detect some vitamins (vitamin B-12) and drugs (morphine).

There are several disadvantages to RIA, which include labor-intensiveness and short shelf life. RIA methods are also heavily regulated (by the Nuclear Regulatory Commission [NRC]) because of their use of radioisotopes. Due to the unique safety hazards posed with this type of testing, facilities require licensing and special procedures for waste disposal. It is for these reasons that many facilities are turning to alternative immunoassay methods.

EIA

In the 1970s, laboratory equipment manufacturers began to develop nonisotope-testing methods including EIA. An enzyme-labeled antigen or antibody is allowed to react with the ligand. An enzyme substrate is then added and a measurement taken. A decrease in substrate or an increase in product (depending on which side of the reaction you are looking at) will quantitate the antigen-antibody reaction. EIA techniques are most commonly applied to uses in serology testing. Other enzymatic methods are the enzyme-linked immunosorbant assay (ELISA) and the enzyme multiplied immunoassay technique (EMIT).

ELISA

One reaction component is adsorbed onto a solid phase surface, which may be magnetic particle, microtiter well, or glass or plastic bead. Attachment to the solid phase separates the free and bound reactants. The free material is washed away and substrate added, which converts the bound complex to a product that is read photometrically, the amount of which is proportional to the analyte present in the sample. ELISA methods have been used extensively for detection of antibodies to viruses and parasites.

EMIT

In this method, no separation step is required. Antibody against the analyte is added along with substrate to the patient sample. The analyte and antibody are allowed to bind. Enzyme-analyte conjugate is added, which binds with excess antibody to form an antigen-antibody complex, which changes the enzyme's activity. The change in activity is proportional to the amount of analyte. EMIT methods are used for detecting a variety of drugs, hormones, and metabolites.

FIA

FIA uses fluorophores (fluorescent substances) as labels just as radioisotopes were used in RIA and enzymes were used in EIA. A fluorometer is used to measure the fluorescent label. Fluorometers are instruments that can select the wavelength of excitation and of emission by using filters. FIA methods are most commonly used to measure therapeutic drugs.

Other testing method principles, components, and limitations

Although we have already viewed a majority of the major methods, there are just a few more of which you must be aware. They are not related to immunoassay, but they are included as part of this lesson. The final analyzer principles we cover include osmometry, turbidimetry, and nephelometry.

Osmometry

Osmometry is used in clinical laboratories to measure the osmolality of a solution (such as plasma, serum, or urine). Osmolality we define as “the particles dissolved in a solution.” In biological fluids, small molecules and ions contribute to the osmolality of a solution. Osmometry, then, measures the concentration of all of the ions and molecules present. There are four properties known as *colligative properties* that we can measure; each of the four is related to each other and to osmolality. These properties are osmotic pressure, boiling point, freezing point, and vapor pressure.

As you increase the osmolality of a solution (add particles to the solution), several things happen. You increase the osmotic pressure of the solution and increase the boiling point of the solution (it will now boil at a higher temperature than pure water). The freezing point of the solution decreases (it will now freeze at a temperature lower than that of pure water), and the vapor pressure is depressed (meaning it is less likely to evaporate than pure water would at the same temperature). The different types of osmometry analyzers use these principles to measure osmolality.

Freezing point depression osmometry

Freezing point depression osmometry (sometimes called “cryoscopy”) measures the osmolality (particle concentration) of a solution by measuring the freezing point of the solution. This freezing point is then compared to the freezing point of a standard sodium chloride solution with a known osmolality. Freezing point is determined by placing a sample into a chamber that contains a sample stirrer and an electronic temperature-sensing device. The sample chamber is then supercooled (the temperature of the sample solution quickly falls below its freezing point). Even though the sample is now below its freezing point, the process has occurred so rapidly that crystallization (freezing) has not yet occurred. Agitating the sample by stirring begins the freezing process. As ice crystals begin to form, heat is released from the solution. The rate of heat released by crystal formation and the rate of heat removal by the chamber quickly reach equilibrium. This equilibrium is reported as the freezing point of the solution.

Vapor pressure (dew point) osmometry

As the vapor pressure of a solution decreases, the osmolality of a solution increases. As vapor pressure decreases, the number of water molecules in a gaseous state above a solution decreases (note, this occurs in a sealed chamber). Having reduced the number of gaseous molecules of water in the head space, you now need to reduce the temperature to reach the dew point temperature, the point where the water molecules condense into a liquid.

After a sample is placed in an enclosed chamber, a current is passed through a thermocouple, decreasing the temperature in the chamber. As the water condenses out of the head space, it falls onto metal plates that detect the condensation and shut off the current to the thermocouple. This response is displayed on a meter that is proportional to the depression of the dew point of the water in the chamber. The analyzer is calibrated using reference materials similar to those we used in the freezing point depression osmometry method.

Colloid osmotic pressure osmometry

Colloid osmotic pressure is a direct measure of the contribution of macromolecules to osmolality. In serum, it is the measure of the contribution that serum proteins make to serum osmolality. In a colloid osmotic pressure osmometer, the measuring cell has two chambers of fluid separated by a semipermeable membrane. A sample containing protein is placed on one side of the membrane (sample side) and a colloid-free saline solution is placed on the other (reference side). The saline on the reference side is in contact with a pressure transducer.

The instrument is initially adjusted to zero by placing saline on both sides of the membrane. During testing, a sample containing protein is placed on the sample side. Fluid moves by osmosis from the saline side across the membrane to the sample side. This causes negative pressure to develop on the reference side where it is detected by the pressure transducer. The resulting negative pressure is equal to the colloid osmotic pressure of the sample.

Colloid osmotic pressure is extremely useful as a clinical measurement. Since proteins in the serum tend to attract water, they are essential to holding fluids in the circulatory system. This type of measurement helps guide intravenous fluid therapy in preventing edemas, particularly pulmonary (lung) edemas. An edema is the abnormal collection of fluid in spaces between cells.

Turbidimetry

Turbidity causes a decrease in the intensity of a light beam as it passes through a solution. The measurement of the light decrease caused by scattering, reflection, or absorption we call turbidimetry. Turbidimetry measures the light path in a *straight line*. The amount of light to pass through the solution is dependent on the concentration of particles in the solution. Instruments for measuring turbidity range from simple spectrophotometers to complex discrete analyzers.

Nephelometry

Nephelometry is a technique that measures the light energy scattered or reflected toward a detector that is not in a direct path to the light source. Most common nephelometers have detectors located at a right angle to the light source. While turbidimetry measured escaping light, nephelometry measures reflected light. To visualize nephelometry, consider the following examples. In a particle-free solution, the light beam would pass through the solution and none of the light would be reflected toward the detector. When particles are present, the light beam hits the particles and reflects off to the side where the beam is detected. The amount of light reflected is proportional to the particles in the solution.

Summary

As technology advances, so will laboratory instrumentation. Companies are already working on techniques using laser beams and infrared light to measure analytes in the body. These techniques will require a beam of light to be passed through the skin and the analyte will be detected while it is still circulating in the bloodstream. The advantages to these types of testing would be enormous. In addition to being painless for the patient, such procedures would protect technicians from exposure to bodily fluids.

The principles and instruments you have learned about in this volume are not all-inclusive. Although we discussed the major principles and types of analyzers, there are many variations to each method. By reading professional literature, you can stay updated on the current technologies and procedures.

Professional knowledge is never wasted; you can use it to advance your military career as well as keep you marketable in the civilian sector.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

027. Analyzers using electrochemistry

1. Why were laboratory managers glad to see the incorporation of electrochemical techniques in laboratory testing?
2. Explain what a “galvanic cell” is and how it works.
3. Explain how half-cells work in potentiometric techniques.
4. Explain how we use coulometric methods to detect chloride concentration.
5. Explain the process behind anodic stripping voltametry.
6. Polarography is most commonly used in analytical chemistry and not clinical chemistry with the exception of which analyte?

028. Analyzers using separation techniques

1. Define chromatography.
2. Describe the two phases of the chromatography process.
3. How does the mobile phase determine the name of a chromatography technique?
4. What is one of the disadvantages of GC?

5. How is the “slurry” passed through the column in LC?
6. What are the two primary advantages of LC over GC?
7. How does HPLC differ from “regular” LC?
8. What is the difference between LC and TLC techniques?
9. Explain how GC/MS analyzers operate.
10. Explain how electrophoresis techniques differ from those of chromatography.
11. Explain how hydration affects an ion’s rate of travel.
12. Describe the purpose of the electrodes in electrophoresis.
13. Why do we use buffered solutions in electrophoresis solutions?
14. What is the purpose of a supporting medium in electrophoresis?
15. What do we use to read an electrophoretic pattern and semiquantify the fractions?

029. Analyzers using immunoassay and other techniques

1. In immunoassay principles, what do we use as a search vehicle?
2. Explain why antigens or antibodies are tagged with a tracer.
3. What are some of the disadvantages of using RIA?
4. Explain the principle used in EIA.
5. What is the difference between the ELISA and the EMIT?
6. What is the purpose of fluorophores in FIA?
7. What is osmometry, and why is it used in the clinical laboratory?
8. What four things happen to a solution when you increase its osmolality?
9. Match the test method characteristic in column A with the appropriate test method name in column B. Each item in column B may be used once, more than once, or not at all.

Column A

- ____ (1) This test method is sometimes called "cryoscopy."
- ____ (2) This method measures the point where water molecules will condense into a liquid.
- ____ (3) In this method, osmosis causes a negative pressure to develop on the reference side of a semipermeable membrane.
- ____ (4) This method measure light decrease caused by scattering, reflection, or absorption.
- ____ (5) This test method has a detector located at a right angle to the light beam.

Column B

- a. Nephelometry.
- b. Vapor pressure (dew point) osmometry.
- c. Freezing point depression osmometry.
- d. Colloid osmotic pressure osmometry.
- e. Turbidimetry.

Answers to Self-Test Questions

025

1. Protein interference. When heated or chemically treated, protein in plasma or serum samples would turn opaque, making photoelectric reading impossible.
2. The AutoAnalyzer used semipermeable membranes to separate the analyte being tested from the interfering proteins.
3. (1) c.
(2) a.
(3) b.
(4) e.
(5) d.
4. (1) f.
(2) a.
(3) b.
(4) d.
(5) c.
(6) e.
5. Accuracy is the ability to determine the actual value of an analyte. Precision is how well the instrument reproduces a result. An instrument may be precise but not accurate.
6. The wavelength of light determines the color of the light and whether or not it can be seen by the human eye.
7. The ultraviolet, visible, and near infrared.
8. A “red” solution appears red because the particles in the solution have absorbed all the wavelengths except the red one. By allowing the red wavelength to pass through the solution, it is seen as a “red” one.
9. Beer’s law states the intensity of the color seen in a reaction is directly proportional to the concentration of the substance being tested.
10. Lambert’s law states that the absorbance of a solution increases linearly when you increase the light path.

026

1. Daily QC programs.
2. Reviewing the manufacturer’s manual ensures you know key points to running the equipment. You may learn items that were not passed on during training or pick up items that were missed when someone else established a program for the equipment.
3. Equipment should be free of chemicals and sample spills because these spills are breeding grounds for diseases, can corrode equipment, coat optical windows (affecting readings), or otherwise create the potential for problems.
4. Because even though the “big picture” looks fine, there may be problems developing on a small scale. By looking at each aspect separately, you can detect these problems sooner and correct them before they reach crisis proportions.
5. That a new method or piece of equipment will yield similar results to the practice currently in use.
6. Method correlation is done by running the same samples on the old and new equipment or method and then comparing the results. If results are widely varied, first ensure that each analyzer is running correctly. If they are, you may need to establish a new reference range for the new procedure or equipment. Be sure to identify the method and reference range on lab reports if both old and new methods will remain in use.
7. Biomedical equipment repair or the factory service representatives.
8. Documentation of equipment maintenance helps shift operators review common problems and solutions should the instrument malfunction as well as support equipment replacement requests.

9. By being familiar with the equipment you are using, you are able to make the distinction between normal and abnormal operations, pick up on subtle hints that a problem is occurring, and troubleshoot these problems to ensure that only proper results are reported.
10. Troubleshooting should start with the most simple (and common) problem and move to the more complex (and less likely) problem.

027

1. Electrochemical techniques allowed the testing of various analytes to be combined into one machine. Laboratory managers now only needed one machine and one technician to do the work that previously needed several machines and technicians.
2. A galvanic cell is the name given to a container housing the process of chemical energy being converted to electrical energy. The galvanic cell is made up of two half-cells, each filled with a metal salt solution. Measurement of voltage generated by the activity of specific ions in the galvanic cell is proportional to analyte concentration.
3. Potentiometry measures the comparison of one electrode potential to the potential of a second electrode. One half-cell maintains a constant voltage (reference electrode), and the second half-cell will contain the unknown solution and have a varying voltage (indicator electrode). By comparing the differences between the electrode potentials, the concentration of your test solution can be calculated.
4. By passing a current through two silver electrodes (immersed in an ionic solution), silver ions are formed. If the solution contains chloride ions, the silver and chloride combine to form silver chloride, an insoluble substance. When all of the chloride ions have been bound, excess silver ions are detected and the process is discontinued. The amount of electricity used is directly proportional to substance produced or consumed by the electrodes.
5. In anodic stripping voltammetry, a negative potential is applied to an electrode, causing the metal ions in the sample to plate the electrode. After a set period of time, the plated ions are removed by applying a positive potential to the electrode. As the ions return to solution, they form a peak characteristic for each metal. The peak height is proportional to the concentration of the analyte.
6. Polarography is used to measure oxygen.

028

1. Chromatography is the separation of substances in a common solvent so that each component may be identified individually. This is done by passing the solvent through a filtering material, allowing some portions to proceed faster than others to a detector where they may be quantified.
2. (1) The mobile phase describes the solvent moving along.
(2) The stationary phase describes a compound coming in contact with the supporting medium column.
3. Chromatography techniques are named based on the type of mobile phase used. If the mobile phase is a liquid, the technique is called "liquid chromatography," and if a gas is used, it is called "gas chromatography."
4. GC can only be used to measure compounds that are naturally volatile or can be converted to a volatile compound. This factor limits GC testing to only 10% to 20% of all known compounds.
5. The slurry is allowed to pass through the column using gravity or with the aid of applied suction or air pressure.
6. LC can be used to separate any compound that is soluble in a liquid phase, and it can be performed at lower temperatures, allowing the testing of thermolabile compounds.
7. In HPLC, the support medium in the column is much smaller and more uniform in size than that in regular LC. The smaller medium results in narrower peaks than those seen in LC.
8. LC uses a straight column to house the filtering material, while TLC techniques use a filtering material in a flat bed.
9. After a sample is introduced into the GC/MS analyzer, it is first converted into a gaseous state. The gas is then placed into an ionizing chamber where it is bombarded by an electron beam. The electron beam causes sample molecules to become positively ionized and these ions are then directed to an acceleration tube and into a mass analyzer. In the mass analyzer, the ions are separated according to their mass-to-charge ratio and the resulting spectrum of masses is scanned by a detector to determine the amount of each component.

10. Electrophoresis techniques use electrical current to separate components while chromatography techniques use a mechanical means.
11. In water, all ions become hydrated or clustered with water molecules. Some ions will cluster with more water molecules than others and this extra weight will cause them to travel more slowly than ions not as heavily burdened.
12. One electrode (the anode) is attached to a positive voltage source and is used to attract negatively charged ions (anions). The other electrode (the cathode) is connected to a negative voltage source and is used to attract positively charged ions (cations).
13. Buffered solutions are used to maintain pH. Proteins may be cationic or anionic, depending on the solution pH. Changing the pH changes the ionic characteristics of the proteins, which may change their rate and direction of movement.
14. A supporting medium keeps the sample and separate fractions from falling through the electrophoresis solution and remixing during the process.
15. A densitometer reads the patterns left on a supporting medium.

029

1. Immunoassays use antibodies and antigens as search vehicles. Since antibodies and antigens are specific for each other, you may search for one by using the other as a search vehicle.
2. Antigens and antibodies are tagged with a tracer; reactions are then read photometrically to determine the analyte of interest.
3. In addition to being labor-intensive, reagent kits are short-lived and often expire before they are used. Because of the unique safety hazards posed with using radioactive materials, facilities must be licensed and have special waste disposal methods.
4. In EIA, an enzyme-labeled antigen or antibody is allowed to react with the ligand. An enzyme substrate is then added and a measurement taken. A decrease in the substrate or an increase in the compound production will quantitate the antigen-antibody reaction.
5. In the ELISA method, one of the reaction components is absorbed onto the surface of a solid phase. Attachment to the solid phase separates the free and bound reactants and the free reactants are then washed away before the enzyme substrate is added. The EMIT method does not have a separation step.
6. Fluorophores are used as labels, just as radioisotopes are used in RIA and enzymes are used in EIA.
7. Osmometry is defined as "the measure of particles in a solution." It is used to measure the osmolality of a solution (such as serum, urine, or plasma).
8.
 - (1) Increases the osmotic pressure of the solution.
 - (2) Increases the boiling point of the solution.
 - (3) Decreases the freezing point of the solution.
 - (4) Depresses the vapor pressure.
9.
 - (1) c.
 - (2) b.
 - (3) d.
 - (4) e.
 - (5) a.

Do the unit review exercises before going to the next unit.

Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter.

72. (025) Analyzers that process samples separately and in their own reaction containers we call
- batch analyzers.
 - discrete analyzers.
 - centrifugal analyzers.
 - belt-cuvette analyzers.
73. (025) Analyzers that have their reaction well located at the outside edge of a disk and that are read while they are spinning we call
- batch analyzers.
 - walkaway analyzers.
 - centrifugal force analyzers.
 - high-speed spectrophotometers.
74. (025) The ability of an instrument to measure only the analyte being tested is said to be the analyzer's
- accuracy.
 - precision.
 - specificity.
 - sensitivity.
75. (025) The lowest value for a test method that can be reported accurately we know as an instrument's
- linearity.
 - accuracy.
 - precision.
 - sensitivity.
76. (025) The ability of a method to determine the actual analyte value is said to be its
- linearity.
 - accuracy.
 - precision.
 - specificity.
77. (025) When white light hits a prism, a rainbow forms. This rainbow of colors we also know as
- a spectrum.
 - an infrared beam.
 - radiant energy.
 - a transmittal beam.
78. (025) The ability of a solution to allow light to pass through it we call
- transmission.
 - optical pass.
 - absorbance.
 - Beer's law.

79. (025) A solution 2 centimeters deep yields a result of 20 grams and a 4-centimeter-deep solution yields a result of 40 grams. This *best* illustrates
- Beer's law.
 - Lambert's law.
 - Richard's second law.
 - the multiplication law.
80. (025) According to Lambert's law, if a solution 5 centimeters deep yields a result of 20 grams, a solution 6 centimeters deep would yield a result of
- 16 grams.
 - 24 grams.
 - 28 grams.
 - 30 grams.
81. (026) All of the following are reasons for keeping equipment clean *except*
- spills corrode equipment.
 - spills keep all gears lubricated.
 - spills may coat optical windows.
 - spills are breeding grounds for diseases.
82. (026) Locking in a value for a standard on a piece of equipment we also know as
- instrument response.
 - instrument assay.
 - quality control.
 - calibration.
83. (026) Your analyzer is "dead"—no power; no response to any controls. Housekeeping was in the facility last night. You
- call in an urgent repair request to biomedical repair.
 - blame housekeeping for breaking your analyzer.
 - check to see if the equipment was unplugged.
 - call for factory service representatives.
84. (027) In coulometry, a current is passed through a solution until excess silver ions are detected. At that time, the current
- continues to bind the excess silver ions.
 - continues to release the bound chloride ions.
 - is shut off, and the electricity used is proportional to the produced analyte.
 - is shut off, and the excess silver ions are proportional to the produced analyte.
85. (027) A technique used primarily in analytical chemistry with the *exception* of the clinical chemistry measurement of oxygen is
- ISE testing.
 - polarography.
 - thermal conductivity.
 - anodic stripping voltametry.
86. (028) How are testing mixtures passed through the column in liquid chromatography methods?
- By use of surfactants.
 - By use of chemical enhancers.
 - By gravity or with the help of applied suction or air pressure.
 - By gravity with the aid of magnetic particles and electrical fields.

-
-
87. (028) By operating at lower temperatures, LC has an advantage over GC in that LC can
- filter gas from slurry.
 - produce smaller peaks.
 - detect virtually all compounds.
 - separate thermolabile compounds.
88. (028) HPLC uses a smaller medium than regular LC, which results in
- HPLC peaks being much narrower than LC peaks.
 - longer retention times for sample detection.
 - filtered material for further testing.
 - the need for increased testing time.
89. (028) Electrophoresis electrodes are normally made out of
- iron because iron is a good electrical conductor and is chemically inert.
 - platinum because platinum is a good conductor and is chemically inert.
 - gold-coated plastic.
 - galvanic half-cells.
90. (029) Allowing an enzyme-labeled antigen or antibody to react with a ligand, adding an enzyme substrate, and then taking a measurement *best* describes
- enzyme-substrate immunoassay.
 - fluorescent immunoassay.
 - enzyme immunoassay.
 - radioimmunoassay.
91. (029) In the ELISA, the purpose of the solid phase is to
- provide detectable material.
 - introduce radiolabeled materials.
 - separate the free and bound reactants.
 - diffuse the sample in a microtiter well.
92. (029) ELISA methods are used extensively for detection of
- allergic reaction antigens.
 - alcohol-induced reactions.
 - lymphoid antibody reactions.
 - antibodies to viruses and parasites.
93. (029) A major difference between the ELISA method and the EMIT is that
- EMIT does not have a separation step.
 - EMIT requires the use of microtiter wells and beads.
 - ELISA separation must occur before the EMIT procedure.
 - the EMIT procedure must occur before ELISA testing can proceed.
94. (029) In vapor pressure (dew point) osmometry, a sample is placed in an enclosed chamber and the temperature is then decreased. What action occurs in the chamber to shut off current to the thermocouple?
- Water evaporates out of the sample and raises the chamber air pressure.
 - Water condenses out of the head space and falls onto metal plates.
 - Sample ions float freely until static discharge occurs.
 - Sample evaporation occurs.

95. (029) In colloid osmotic pressure osmometry, fluid moves by osmosis from the saline side of the membrane to the sample side of the membrane. This results in a
- a. positive pressure on the sample side.
 - b. negative pressure on the sample side.
 - c. positive pressure on the reference side.
 - d. negative pressure on the reference side.

Please read the unit menu for unit 7 and continue. ➔

Unit 7. Biowarfare and Terrorism

030. Understanding biowarfare and bioterrorism	7-1
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SEPTEMBER 11, 2001—the events of that day certainly opened our nation’s eyes to the fact that the previously simmering cauldron of terrorism had reached a boiling point. That day indicated that terrorists will stop at nothing and know no bounds when it comes to carrying out their dastardly objectives. As we illustrate in this unit, the threat is real and the potential of a catastrophic biological attack against the United States or its interests exists every minute of every day. Every laboratory technician must be prepared to respond to this threat.

As we stated above, bioterrorism (BT) is a real threat to the United States and the Western world. If used, bioterrorism or biowarfare has the potential to cause great devastation in the civilian community and drain military resources in that manner, or they may exact a toll directly on the battlefield.

030. Understanding biowarfare and bioterrorism

In the past, there may have been some lack of concern in some of us about the threat of biological warfare. Unfortunately for us, the dangers posed by biological weapons did not disappear when the United States began to unilaterally dismantle our own biological weapons program in 1969. The dangers also did not vanish with the signing of the Biological and Toxic Weapons Convention of 1972 or with the end of the Cold War. The threat is still very real; only by planning and investing in the right defensive measures can we minimize the likelihood that biological weapons will not be used against us in the future. If they are used, hopefully, our planning will reduce the risks, disruptions, and casualties that they could have caused.

What is the medical laboratories’ role in all of this? Where do we, as enlisted medical laboratory technicians, fit into the plan? Let’s take a look at the 4T0X1 role in biowarfare and bioterrorism as it stands today. As we well know, with the terrorist actions within the United States, such as the World Trade Center and the Pentagon bombings, all of our roles have changed and are constantly being redefined because of the new and unconventional threats that have been posed against the United States. In other words, as new threats present themselves, our roles again must change. This lesson gives you basic information about the history of biowarfare and bioterrorism, the characteristics of biological attacks, the Laboratory Response Network (LRN), defining and identifying biosafety agents, biosafety levels (BSL), and specimen packaging and shipping.

History of biological warfare and bioterrorism

Biowarfare and bioterrorism we define as “the intentional or alleged use of viruses, bacteria, fungi, and toxins to produce death or disease in humans, animals or plants.” BT events can be announced (overt) or unannounced (covert). The use of biological weapons and ways to make them a useful means of waging war have been recorded again and again during history. As early as the sixth century BC, the Assyrians poisoned enemy wells with rye ergot, which incapacitated their enemies with cramps, spasms, and gangrene. There was Solon’s use of diarrhea-producing herb hellebore during the siege of Krissa.

More recently, there is evidence that during World War I, German agents in the United States inoculated horses and cattle with glanders before they were shipped to France. The Japanese, in 1937, initiated an elaborate biological warfare program in a laboratory complex that was code named “Unit 731.” Studies continued there until the complex was leveled by fire in 1945. A post–World War II investigation of Unit 731 revealed that the Japanese were conducting research on numerous organisms and that the experiments were being carried out on prisoners of war. Of the almost 1,000 human autopsies that were carried out at Unit 731, it was found that most of the victims had been exposed to aerosolized anthrax. In 1943 the United States began research into the offensive use of biological agents. The United States conducted this research at a small National Guard airfield, Fort

Detrick, Maryland. We also produced biological agents at other sites in the United States until 1969. In 1969, by executive order, President Nixon stopped all offensive biological and toxin weapon research and production. Between May 1971 and May 1972, all stockpiles of biological agents and munitions from the US program were destroyed. Agents destroyed included the following: *Bacillus anthracis*, botulinum toxin, *Francisella tularensis*, *Coxiella burnetii*, Venezuelan equine encephalitis virus, *Brucella suis*, and Staphylococcal enterotoxin B. In 1971 the United States and many other countries signed the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, commonly called the Biological Weapons Convention. This treaty prohibited the stockpiling of biological agents for offensive military purposes and also forbade research into the offensive employment of biological agents. Both the former Soviet Union and the government of Iraq were signatories to this treaty. As we well know, despite this agreement among the nations, biological warfare research has continued to flourish in many countries considered hostile to the United States.

Why we need to be ready

Biological weapons are unfortunately characterized by low visibility, high potency, substantial accessibility, and relatively easy delivery. The basic facts are well known: a millionth of a gram of anthrax constitutes a lethal dose. A kilogram, depending on meteorological conditions and means of delivery, has the potential to kill hundreds of thousands of people in a metropolitan area. These small quantities make the concealment, transportation, and dissemination of biological agent relatively easy. Many of these agents—bacteria, viruses, and toxins—occur naturally in the environment. Moreover, many are used for wholly legitimate medical purposes (such as the development of antibiotics and vaccines), and much of the technology required to produce and “weaponize” them is available for civilian or military use. Unlike nuclear weapons, missiles or other advanced systems are not required for the delivery of biological weapons. Since aerosolization is the predominate method of dissemination, extraordinary low technical methods, including agricultural crop dusters, backpack sprayers, and even purse-size perfume atomizers will suffice. Small groups of people with modest finances and basic training in biology and engineering can develop an effective biological weapons capability. Recipes for making biological weapons are even available on the Internet.

These unique characteristics make both military and civilian society vulnerable to biological weapons. It is true that their delayed effects and vulnerability to weather make these weapons ill-suited to military purposes such as seizing territory. Biological weapons can, however, effectively impede the mobilization and massing of troops that would be required to sustain our role in a conventional conflict. Most disturbingly, they can be used to threaten civilian populations and create mass panic. Used this way, biological weapons can achieve military goals by undercutting civilian support necessary for military operations or by holding civilians hostage to prevent military operations

—JAMA, 6 August 1997

Laboratory Response Network

The above quote clearly describes why we need to be ready; to be aware of our responsibilities; and to be well trained to fulfill our responsibilities if a biological attack were to occur. We have seen this threat become a reality. The need for trained laboratory professionals to respond to such incidents has created the need for the LRN. The Centers for Disease Control and Prevention (CDC) has been given the responsibility to provide our nation with a laboratory system that delivers accurate and timely identification of any agent causing a public health threat, including both naturally occurring diseases and organisms that could be used in a biological attack. The CDC, in collaboration with the Association of Public Health Laboratories (APHL) and the Federal Bureau of Investigation (FBI), established the LRN to develop the federal, state, and local public health laboratory capacity to

respond to bioterrorism events. This network is a strategic partnership designed to link front-line clinical microbiology laboratories in hospitals and other institutions to state and local public health laboratories and supports advanced capacity of clinical, military, veterinary, agricultural, water and food-testing laboratories at the federal level. This partnership operates both domestically and internationally. Your role as a medical laboratory technician is essential to this program and can help to save lives.

The purpose of LRN

The fundamental goal of the LRN is to enhance US laboratory capacity for preparedness and ability to respond to an act of bioterrorism by providing a shared network of civilian, public health, and military laboratories to facilitate rapid detection and analysis of both chemical and biological agents. The LRN consists of over 120 core reference public health laboratories from both the military and civilian sectors that provide confirmatory testing for agents at biosafety levels 3 and 4. There are an estimated 2,500 sentinel laboratories that play an important role in reporting possible biological agent outbreaks and ensure that specimens are sent to the appropriate reference laboratory for confirmation. The LRN designates laboratories into one of four levels, each having its own unique role.

The role of the Air Force in LRN

The following is an excerpt of a memorandum from the Air Force surgeon general, Paul K. Carlton, Jr., Lieutenant General, USAF, MC, CFS, released in May 2001 about the National Laboratory Response Network:

The Centers for Disease Control and Prevention (CDC) has established the National Laboratory Response Network (NLRN), a collaborative effort between the CDC and the Association of Public Health Laboratories (APHL). The NLRN is an early warning network to detect a covert release of pathogenic agents by utilizing procedures established by the CDC. It is based on grouping laboratories into one of four different levels, A through D, according to their ability to support the diagnostic needs presented by a bioterrorism event. Laboratories able to conduct basic tests to rule out a particular biological agent can operate at Level A. Recognizing that most DOD clinical laboratories currently have the capabilities to operate at Level A, and that this added capacity would enhance the NLRN, the CDC is looking at DOD laboratories in the United States and its territories to enhance its NLRN. Additionally, the CDC and HQ USAF/SG have entered into a Memorandum of Agreement to support the establishment and coordinate collaboration towards the development of a National Medical Early Warning System of which the NLRN is an important component. In support of the NLRN and homeland defense, all AF medical laboratories in the United States will participate, at a minimum, at Level A.

General Carlton's statement clearly defines our role in the LRN and our need to be well trained so we can fulfill our responsibilities if needed.

LRN laboratories

The LRN operates as a network of laboratories (laboratory levels designated A: hospital laboratories; B: state health laboratories; C: CDC; and D: CDC and US Army Medical Research Institute of Infectious Diseases [USAMRIID]), which are placed within a designated level based on their capabilities. The laboratories are classified based on their progressively stringent levels of safety, containment, and technical proficiency, which are necessary to perform the essential *rule-out, rule-in, and referral* functions required for biological agent identification. Easy and open network access provides all public health laboratories with a means to accept and transfer specimens (we discuss specimen collection and shipping later) where definitive testing can be performed. This allows early detection and *suspect-level* identification at the local clinical laboratory level, which is subsequently supported by a more advanced capacity for rapid *presumptive and confirmatory-level testing* at state and larger metropolitan public health laboratories. The Air Force laboratories are a very important part of this network. The following chart briefly describes each of the LRN levels.

LRN Laboratory Level	Scope of Responsibilities
Level A	<i>Rule-out or Refer</i> Assess risks for aerosols BSL-2 Detect early (presumptive) cases
Level B	<i>Rule-in and Refer</i> Isolate and identify agents BSL-3 [recommended] Performs susceptibility testing
Level C	<i>Rule-in and Refer</i> BSL-3 Rapid identification
Level D	<i>Confirm, Validate, and Archive</i> BSL-4 Perform high-level characterization Probe for universal agents

Level A

The function of a Level A laboratory is to detect the intentional dissemination of biological agents. Level A laboratories are generally hospital/clinical laboratories with low-level biosafety facilities. They are generally biosafety Level 2 laboratories. They use clinical data and standard microbiology tests to decide which specimens and isolates should be forwarded to one of the higher-level biocontainment laboratories. We discuss some key tests that can be performed in a Level A laboratory to recognize cultivable agents of bioterrorism later. The Level A laboratory, as all other laboratories, must have a clearly defined plan in place if there is a need to identify biological agents from either an overt or covert event. The following are some questions your Level A laboratory should be asking itself. What is the BT level of my lab? Is my laboratory active in LRN? Where is the nearest higher-level LRN laboratory? What guidelines do we follow to package and ship biological agents? When should I call for help? The staff of a Level A laboratory must be trained in the safe collection, packaging, labeling, and shipping of specimens that might contain biological agents. Even though the use of a biological agent for terrorism is at a fairly low probability, if it were to happen, it could have very large, potentially devastating consequences—we need to be prepared!

Level B

Level B laboratories we define as having core capacity for agent isolation and presumptive-level testing of suspect specimens. The Level B laboratories are state and local public health agency laboratories that can test for specific agents and forward organisms or specimens to higher-level biocontainment laboratories. Level B laboratories minimize false positives and protect Level C laboratories from overload. Ultimately, the Level B laboratories will have the capacity to perform confirmatory testing and distinguish drug susceptibility.

Level C

Laboratories at Level C have advanced capacity for rapid identification. The Level C laboratories, which could be located at state health agencies, academic research centers, or federal facilities, perform advanced and specialized testing. The Level C laboratories have the capacity to perform toxicity testing and employ advanced diagnostic technologies (e.g., PCR and molecular fingerprinting). Level C laboratories also participate in the evaluation of new tests and reagents and determine which assays could be transferred to Level B laboratories.

Level D

The Level D laboratories are designed to have the highest level of agent containment and the expertise in the diagnosis of rare and dangerous biological agents. These laboratories are specialized federal laboratories, such as the CDC, with unique experience in the diagnosis of rare diseases (e.g., smallpox and Ebola). The Level D laboratories also develop or evaluate new tests and methods. These laboratories have the resources to maintain a strain bank of biological agents. Level D laboratories maintain the highest biocontainment facilities and are able to do all tests performed by Level A, B, and C laboratories, as well as additional confirmatory testing and characterizations, as needed. They also have the capacity to detect genetically engineered agents.

Biological agents

As we stated earlier, we define biowarfare and bioterrorism as “the intentional or the alleged use of viruses, bacteria, fungi, and toxins to produce death or disease in humans, animals, or plants.” Which biological agents would most likely be used by bioterrorists? The following chart is a partial list of biological agents that could be used by the enemy.

Agent	Member	
Bacterial	Anthrax	Shigellosis
	Brucellosis	Tularemia
	Cholera	Typhoid fever
	Meloidosis	Plague (pneumonia)
Rickettsial	Epidemic typhus	Rocky Mountain spotted fever
	Q fever	Scrub typhus
Chlamydial	Psittacosis	
Fungal	Coccidioidomycosis	Histoplasmosis
Viral	Argentine hemorrhagic fever	Korean hemorrhagic fever (Hantaan)
	Bolivian hemorrhagic fever	Lassa fever
	Chikungunya fever	Omsk hemorrhagic fever
	Crimean-Congo hemorrhagic fever	Rift Valley fever
	Dengue fever	Russian spring summer encephalitis
	Ebola	Venezuelan equine encephalitis
	Eastern equine encephalitis	Yellow fever
	Influenza	
Toxins	Botulinum toxins	Ricin
	Clostridium toxins	Saxitoxin
	Mycotoxins	Staphylococcal enterotoxins
	Palytoxin	Tetrodotoxin

Centers for Disease Control and Prevention

As a part of the congressional initiative that was initiated in 1999 to upgrade national public health capacities for response to acts of biological terrorism, the CDC was designated as the lead agency for overall public health planning. A Bioterrorism Preparedness and Response Office had been formed within the CDC to help target several areas for initial preparedness activities, including planning, improving surveillance and epidemiologic capabilities, rapid laboratory diagnosis, enhanced communication, and medical therapeutic stockpiling. To effectively direct these preparedness efforts, however, the biological agents towards which these efforts were to be targeted had to first be formally identified and placed into some system of priority order. Many biological agents can cause illness in humans, but not all are capable of affecting public health and our medical infrastructures on a large scale. Using the combined efforts and knowledge of both military and civilian experts in biological agents, a system was established.

Categorizing biological agents

In April 2001, the CDC published the Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response and in it said, “The U.S. public health system and primary care providers must be prepared to address varied biological agents, including pathogens that are rarely seen in the United States.” In their plan, they included the categorization of critical biological agents. These categories were initially proposed in 1999 by a combined group of academic infectious disease health experts, Department of Health and Human Services agency representatives, civilian and military intelligence experts, and law enforcement experts. These categories are described below.

Category A

Category A agents are high-priority agents that include organisms that pose a risk to national security because they can be easily disseminated or transmitted person-to-person; cause high mortality, with potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness. Category A agents include:

1. *Variola major* (smallpox).
2. *Bacillus anthracis* (anthrax).
3. *Yersinia pestis* (plague).
4. *Clostridium botulinum* toxin (botulism).
5. *Francisella tularensis* (tularemia).
6. Filoviruses (e.g., Ebola hemorrhagic fever and Marburg hemorrhagic fever).
7. Arenaviruses (e.g., Lassa fever and Argentine hemorrhagic fever).

Category B

These agents are the second highest priority agents and include those that are moderately easy to disseminate; cause moderate morbidity and low mortality; and require specific enhancements of CDC’s diagnostic capacity and enhanced disease surveillance. Category B agents include:

1. *Coxiella burnetti* (Q fever).
2. *Brucella* species (brucellosis).
3. *Burkholderia mallei* (glanders).
4. Alphaviruses (e.g., Venezuelan encephalomyelitis and eastern and western equine encephalomyelitis).
5. Toxins (e.g., Ricin, *Clostridium perfringens*, and *Staphylococcus enterotoxin B*).
6. A subset list of B agents includes pathogens that are food- or waterborne. These pathogens include:
 - a) *Salmonella* species.
 - b) *Shigella dysenteriae*.
 - c) *Escherichia coli* O157:H7.
 - d) *Vibrio cholerae*.
 - e) *Cryptosporidium parvum*.

Category C

The third highest priority of agents includes “emerging threat agents” that could be engineered for mass dissemination in the future because of availability; ease of production and dissemination; and potential for high mortality and major health impact. Category C agents include:

1. Nipah virus.
2. Hantaviruses.
3. Tick-borne hemorrhagic fevers.

4. Tick-borne encephalitis viruses.
5. Yellow fever.
6. Multidrug-resistant tuberculosis.

Surfacing pathogens

The CDC believes that preparedness for category C agents requires ongoing research to improve disease detection, diagnosis, treatment, and prevention. They also believe that knowing in advance which newly surfacing pathogens may be used by terrorists is obviously impossible; therefore, linking bioterrorism preparedness efforts with ongoing disease surveillance and outbreak response activities, as defined by them in their emerging infectious disease strategies, is critical.

LRN—recognizing biological agents at the lowest level

Laboratories must prepare to rapidly recognize biological agents in order to protect themselves and the public from disease. As we stated earlier, the scope of responsibilities for Level A laboratories is to *rule-out or refer* potential biological agents to other LRN laboratories, and that minimally all Air Force laboratories are expected to function at this level. This process of *rule-out or refer* obviously includes the ability of the laboratory to detect early (presumptive) cases. Generally, your laboratories' microbiology sections are not in the business of detecting biological agents. Because most biological agents rarely cause naturally occurring diseases, we need to enhance our ability at a local level to presumptively identify these agents. If your laboratory has the ability to identify common pathogens presented to us daily by our patients, we probably already have the ability to perform most presumptive identifications on potential biological agents.

Steps to identification

The steps that we use to identify these agents are not unlike those we use routinely to identify bacteria in the laboratory. Observations of the medium where the organism is growing, the colony characteristics and any obvious odor of the microorganism is the first step to early presumptive identification. Secondly, perform a Gram stain. Once you know the Gram stain results, following normal microbiology protocol (flow charts) should be sufficient to perform presumptive identifications of the agents. The following chart briefly describes many of the key tests that you can perform to presumptively identify cultivable biological agents.

Organism (Agent)	Gram Stain	BAP Observations	Oxidase	Catalase	Motility	Other Confirmatory Tests
<i>Bacillus anthracis</i> (anthrax)	Gram-positive rods; large and irregular, spores may be present	Large, nonhemolytic	N/A	Pos.	Neg.	None, wet mount motility from fresh plate (< 6 hrs. old) preferred.
<i>Bacillus</i> species (brucellosis)	Small gram-negative coccobacilli, no growth on MAC	Grayish, may take 48 hrs. to grow	Pos.	Pos.	Neg.	Rapid urea-positive
<i>Francisella tularensis</i> (tularemia)	Very tiny faintly staining gram-negative rod or coccobacilli, no growth on MAC	BAP: no growth, (even around staphylococcus), grows on CHOC	Neg.	Neg. or weak	Neg.	Beta-lactamase-positive
<i>Yersinia pestis</i> (plague)	Not applicable, grows on MAC or EMB	Good growth, may have fried egg colony	Neg.	N/A; do ID kit	Neg.	Rapid urea-negative, nonmotile at 22°C, rhamnose-negative and negative with <i>Shigella</i> antisera. Do

Organism (Agent)	Gram Stain	BAP Observations	Oxidase	Catalase	Motility	Other Confirmatory Tests
						not wait for confirmatory tests to report to health department.
<i>Burkholderia mallei</i> (glanders)	Gram-negative coccobacilli, may not grow on MAC	May take 48 hrs. to grow, nonhemolytic and nonpigmented	Variable	Pos.	Neg.	Polymyxin B or colistin resistant; arginine-positive, nonfermenter
<i>Burkholderia pseudomallei</i> (melioidosis)	Not applicable, grows on MAC or EMB	May take 48 hrs. to grow; strong unpleasant odor, may become wrinkled with age, nonpigmented	Pos.	N/A; do ID kit	Pos.	Polymyxin B or colistin resistant; arginine-positive, nonfermenter

Notification procedures of presumptive positive cultures

If your laboratory has presumptively identified through routine culturing and the performance of *key* tests any of the cultivable biological agents that were listed in the CDC categories (A–C), *make* this information known to higher levels of authority *immediately*. Remember, CDC Category A agents have been defined as having the potential of causing high mortality and public panic and require special action for public health preparedness. Your laboratory officer and chief of pathology are the first people you will need to notify. They, in turn, will consult with the closest Level B or Level C laboratory and refer the specimen for confirmation. They will also brief individuals within your medical treatment facility (MTF) (such as the commander and preventive medicine) about the incident. As required, they report the information to local, state, and regional public health offices, the CDC, the USAMRIID, or the FBI for further guidance. Rapid and effective communication of what has been found allows *professionals* to decide if the *presumptive* identification merits full activation of the FBI. Communication also allows for local, state, and US regional laboratories to issue alerts to other laboratories to ensure no other similar isolates have occurred elsewhere.

Biosafety levels

Whether you work in a Level A or Level D laboratory, understanding the principles of biosafety and the BSLs recommended for your work area is important for your own personal safety and the safety of the people with whom you work. Most of us work in Level A laboratories, which minimally require a BSL–2 for the safety of their workers. At best, we will be working in Level B laboratories requiring BSL–3 conditions. Beyond operating at the required BSLs, all laboratories must also comply with regulations, policies, and commonly accepted procedures for handling bloodborne pathogens.

Assessing BSL factors

The factors that are taken into consideration when assessing what BSL your laboratory has are as follows: the agents involved, practices/techniques, safety equipment (primary barriers), and facilities (secondary barriers). In this lesson, we only do a brief review of the factors involved with each level; a further discussion of BSLs will be included in volume 1 of the 4T051B CDC. The following is a summary of the recommended BSLs for infectious agents as defined by the CDC.

BSL-1

Listed below are the factors involved for BSL-1:

- *Agent.* Well-characterized agents not known to consistently cause disease in healthy adults and of minimal potential hazard to lab personnel and environment.
- *Practices.* Standard microbiology practices.
- *Safety Equipment (Primary Barriers).* None required.
- *Facilities (Secondary Barriers).* Sink required for handwashing.

BSL-2

The factors involved for BSL-2 are as follows:

- *Agent.* Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure.
- *Practices.* BSL-1 practices plus limited access, biohazard warning signs, “sharps” precautions, biosafety manual defining any needed waste decontamination or medical surveillance policies.
- *Safety Equipment (Primary Barriers).* Primary barriers = Class I or II biosafety cabinets (BSC) or other physical containment devices used for all manipulations of agents that cause slashes or aerosols of infectious materials; personal protective equipment (PPE); lab coats; gloves; face protection as needed.
- *Facilities (Secondary Barriers).* BSL-1 plus autoclave available.

BSL-3

Below are the factors involved for BSL-3:

- *Agent.* Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.
- *Practices.* BSL-2 practices plus controlled access, decontamination of all waste, decontamination of lab clothing before laundering, and baseline serum.
- *Safety Equipment (Primary Barriers).* Primary barriers = Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPEs; protective lab clothing; gloves; respiratory protection as needed.
- *Facilities (Secondary Barriers).* BSL-2 plus physical separation from access corridors; self-closing double-door access; exhausted air not recirculated; negative airflow.

BSL-4

These are the factors involved for BSL-4:

- *Agent.* Dangerous/exotic agents that pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission.
- *Practices.* BSL-3 practices plus clothing change before entering, shower on exit, and decontamination of all material on exit from facility.
- *Safety Equipment (Primary Barriers).* Primary barriers = all procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive-pressure personnel suit.
- *Facilities (Secondary Barriers).* BSL-3 plus located in a separate building or isolated zone, dedicated supply and exhaust vacuum, and decontamination system, and other requirements as needed.

Specimen collection of infectious agents

Now that we have an understanding of how to protect our work areas and ourselves by utilizing the proper BSL when working with biological agents, what specimens are required for the identification of the suspected pathogens? Generally, there are two major types of samples that you collect and process in your laboratory. First are your everyday *clinical specimens*, which are defined as any human or animal material including, but not limited to, excreta, blood, and its components, tissue and tissue fluids collected for the purposes of diagnosis, but excluding live infected animals. Clinical specimens resulting from medical practice and research are considered a negligible threat to the public health. In the case of biological agents, you work with what we define as *infectious substances*. Infectious substances are defined as substances containing a viable microorganism, such as bacterium, virus, rickettsia, parasite, or fungus, that is known to or is reasonably believed to cause disease in humans or animals. For the purposes of specimen collection and transport safety, we consider the terms “infectious substances” and “infectious materials” synonymous.

General rules for safe specimen collection

Before we discuss some of the specific specimen requirements for infectious substances, let's do a quick review of general safety practices to use while collecting any infectious or clinical laboratory specimen. Listed below are four simple rules to follow:

1. Perform all specimen collection procedures while wearing gloves, a lab coat, and, where appropriate, masks and/or goggles.
2. All primary specimen containers must be leak-proof and transported within a sealable, leak-proof plastic bag having a separate compartment for paperwork.
3. Never transport syringes with needles to the laboratory. Instead, transfer their contents to a sterile tube or remove the needle with a protective device. In either case, recap the syringe and place it in a sealable, leak-proof plastic bag.
4. Do not transport leaking specimen containers to the laboratory or process them. Notify the provider of the leaking container and explain the potential compromised nature of the results if the processing is continued and ask for a repeat specimen. If a new one is submitted, dispose of the leaking one properly.

These “four rules” are just the basis of the specimen collection safety practices you must use in your laboratory. Reports on laboratory-acquired infections (LAI) reveal that most LAIs are caused by bacteria (43%), followed by viruses (27%), and rickettsiae (15%). The most common types of exposure, resulting in LAIs, are inhalation, ingestion, inoculation, and contamination of skin and mucous membranes. About two-thirds of all LAIs resulted from direct work with the infectious agents. Laboratory accidents were the second greatest source of LAIs, with approximately 70% of the accidents caused by splashes or sprays, needle sticks, and cuts. Follow the rules—don't become a statistic!

Specimen selection

It should be of no surprise to you that the specimen selection and collection methods for infectious substances are not that much different from those for everyday clinical specimens. The following table gives you an overview of the types of specimens that may be ordered for the isolation and identification of the various biological agents.

Agent	Types of Specimen
Anthrax	Cutaneous form—vesicle swabs. Gastrointestinal form—stool or blood. Inhalation form—sputum or blood.
Brucellosis	Acute, subacute, or chronic stage—serum, blood, bone marrow, spleen, or liver.
Botulism	Presents various clinical syndromes—specimen of choice for confirming serum, wound/tissue, or stool and incriminating food dependent on the syndrome.

Agent	Types of Specimen
Plague	Pneumonic—sputum/throat, bronchial/tracheal wash, and blood.
Tularemia	Pneumonic—sputum/throat, bronchial/tracheal wash, and blood.
Smallpox	Rash—biopsy specimen, scabs, and vesicular fluid.

Specimen packaging and shipping procedures

Once you collect the proper specimen, how do you safely ship it to the LRN referral laboratory? As Level A sentinel laboratories, a clear understanding of the proper requirements for packaging and shipping specimens to the reference LRN laboratory is essential. Shipping infectious substances versus clinical specimens differs slightly. The shipping of clinical specimens we define later. Classify any specimen (e.g., swabs, scrapings, body fluids, tissue) and/or suspected organisms that are referred to a higher-level reference LRN laboratory to rule out and/or identify any possible biological agent as “infectious substances”; package and ship them accordingly.

Packaging requirements for infectious substances

The packaging material for these shipments must be United Nations (UN) certified for infectious substances and designated as “UN 4G/CLASS 6.2.” A basic triple-packaging system is used with some additional specifications, labeling, and documentation requirements that are not used when we ship clinical specimens. The following table briefly outlines the primary, secondary, and outer packaging requirements, as shown in figure 7-1.

Primary Receptacle	<ol style="list-style-type: none"> 1. The container must be <i>watertight</i> and may include glass, plastic, metal, or screw-cap tubes. 2. It must have a specimen identification label on it. 3. To ensure a leak-proof seal, the screw caps must be fastened with tape, shrink seals, or other comparable packaging. 4. Absorbent material must surround each primary receptacle and be in sufficient amounts to absorb the contents of the primary container.
Secondary Packaging	<ol style="list-style-type: none"> 1. This container must also be watertight. 2. The primary receptacle must be placed within the secondary packaging and surrounded by absorbent material. 3. Affix an itemized list of the contents (e.g., <i>E. coli</i> on 5 ml slant) to the secondary packaging. 4. Label the secondary package with the following information: name, address, and telephone number of shipper.
Outer Packaging	<ol style="list-style-type: none"> 1. Adequate strength construction. 2. Place secondary packaging (along with proper forms required from higher-level laboratories) within the outer packaging unit. 3. Labels required on outer packaging: <ol style="list-style-type: none"> a) Address label: higher-level laboratories address and phone number, and shipper's name, address, and phone number. b) Infectious substance label (fig. 7-2). c) Completed UN 2814 label.

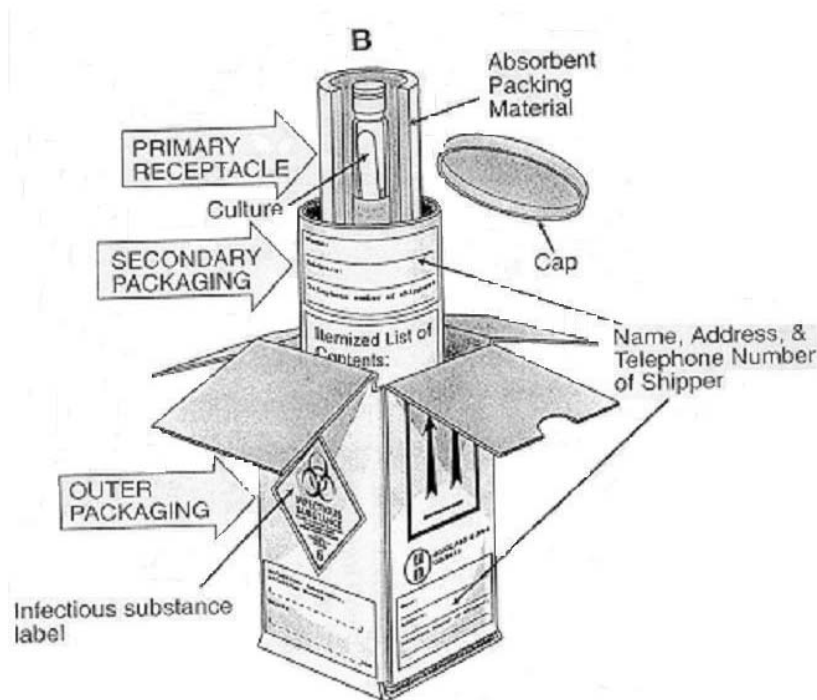


Figure 7-1. Packaging requirements for infectious substances.



Figure 7-2. Infectious substance label.

Transportation

If the infectious substances to be shipped require dry ice or cold packs, place the outer packaging container into an overpack container. The labels and forms required on the overpack include, but are not limited to, the higher-level lab's address and phone number; shipper's name, address, and telephone number; an infectious substance label; a completed UN 2814 label; shipper's Declaration for Dangerous Goods form; and a label for ice/dry ice. Regulations on the transportation of biological agents are aimed at ensuring that the public and the workers in the transportation chain are protected

from exposure to any agent that might be in the package. Protection is achieved through: (1) the requirements for rigorous packaging that will withstand rough handling and contain all liquid materials within the package without leakage to the outside; (2) appropriate labeling of the package with the infectious substance symbol, biohazard symbol, and other labels to alert the workers in the transportation chain to the hazards of the package; (3) documentation of the hazardous contents of the package should such information be required in an emergency situation; and (4) training of workers in the transportation chain to familiarize them with the hazardous contents, enabling them to properly respond to emergency situations.

Our complete adherence to all packaging and shipping requirements is a must in order to minimize the possibility of contaminating yourself or anyone who comes in contact with the samples. Contact your local shipping company for additional requirements prior to shipping any infectious substances. Overnight delivery and package tracking capabilities are a must when shipping these types of samples.

NOTE: The role of the 4T in the LRN is constantly evolving. For our most current requirements, consult your laboratory officer and the AFMS Web site. The requirements for specimen collection, packaging, and shipping are also subject to change. This lesson only gives the reader a basic idea of the importance of the processes—not exact guidelines. Your laboratory OIs should contain complete instructions on these subjects. Contact the Center for Clinical Laboratory Medicine (CCLM) at the Armed Forces Institute of Pathology (AFIP) for guidance. You can also find current requirements on the CDC Web site, specifically in the *Biosafety in Microbiology and Biological Laboratories*, United States Department of Public Health and Human Services, 4th ed, 1999.

Self-Test Questions

After you complete these questions, you may check your answers at the end of the unit.

030. Understanding biowarfare and bioterrorism

1. Define biowarfare and bioterrorism.
2. What two forms can bioterrorism events take?
3. What occurred between May 1971 and May 1972?
4. What did the Biological Weapons Convention do?
5. With what two other agencies did the CDC collaborate to establish the LRN?
6. What is the fundamental goal of the LRN?

7. How many reference and sentinel laboratories are there in the LRN network, and what are their individual functions?
8. In General Carlton's memorandum, he stated that in support of LRN and homeland defense, all Air Force medical laboratories in the United States will participate in the LRN minimally at what level?
9. How are the laboratories of the LRN assigned to their designated levels?
10. List the scope of responsibilities for the Level A LRN laboratories.
11. List the scope of responsibilities for the Level D LRN laboratories.
12. What is the function of a Level A laboratory?
13. What do the Level A laboratories use to decide which specimens are to be forwarded to a higher-level laboratory?
14. At what performance capacity do Level C laboratories perform?
15. A Bioterrorism Preparedness and Response Office had been formed within the CDC to help target what areas of the initial preparedness activities?
16. Define Category A biological agents.
17. Define Category B biological agents.
18. Define Category C biological agents.
19. What is the first step in the presumptive identification of a potential biological agent?

20. If you have presumptively identified a biological agent through routine culturing and the performance of *key* tests, whom do you notify first with this information?
21. List the four factors that you must take into consideration when assessing the BSL of your laboratory.
22. List the “practices” required for a BSL-2.
23. List the “facilities (secondary barriers)” required for a BSL-4.
24. Define infectious substance.
25. List the three clinically different forms of anthrax and the specimens we would collect to identify them.
26. What type of packaging system do we use to ship infectious substances?
27. List the labeling requirements for the “outer packaging” when shipping infectious substances.
28. When shipping biological agents, protection of transportation workers and the public is achieved through what four general rules?
29. List the sources that you can use to obtain the most up-to-date information about the LRN.

Answers to Self-Test Questions

030

1. The intentional or alleged use of viruses, bacteria, fungi, and toxins to produce death or disease in humans, animals, or plants.
2. Announced (overt) or unannounced (covert).
3. All stockpiles of biological agents and munitions from the US biological program were destroyed.
4. The treaty prohibited the stockpiling of biological agents for offensive military purposes and also forbade research into the offensive employment of biological agents.
5. The Association of Public Health Laboratories and the FBI.
6. To enhance US laboratory capacity for preparedness and ability to respond to an act of bioterrorism by providing a shared network of civilian, public health, and military laboratories to facilitate rapid detection and analysis of both chemical and biological agents.
7. The LRN consists of over 120 core reference public health laboratories from both the military and civilian sectors that provide confirmatory testing for agents at biosafety levels 3 and 4. There is an estimated 2,500 sentinel laboratories that play an important role in reporting possible agent outbreaks and ensure specimens are sent to the appropriate reference laboratory for confirmation.
8. Minimally at Level A.
9. The LRN operates as a network of laboratories, which are placed within a designated level based on their capabilities.
10. Level A responsibilities: *Rule-Out or Refer*; assess risks for aerosols; BSL-2; and detect early (presumptive) cases.
11. Level D responsibilities: *Confirm, Validate, and Achieve*; BSL-4; perform high-level characterization; and probe for universal agents.
12. The function of the Level A laboratory is to detect intentional dissemination of biological agents.
13. Clinical data and standard microbiology tests to decide which specimens and isolates should be forwarded to one of the higher-level biocontainment laboratories.
14. The Level C laboratories have the capacity to perform toxicity testing and employ advanced diagnostic techniques (e.g., PCR and molecular fingerprinting).
15. The areas include planning, improving surveillance and epidemiologic capabilities, rapid laboratory diagnosis, enhanced communication, and medical therapeutic stockpiling.
16. These are high-priority agents that include organisms that pose a risk to national security because they can be easily disseminated or transmitted person-to-person; cause high mortality, with potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness.
17. These are the second highest priority agents and include those that are moderately easy to disseminate; cause moderate morbidity and low mortality; and require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.
18. The third highest priority agents include "emerging threat agents" that could be engineered for mass dissemination in the future because of availability; ease of production and dissemination; and potential for high mortality and major health impact.
19. Observation of the media where the organism is growing, the colony characteristics, and any obvious odor of the microorganism is the first step to early presumptive identification.
20. Your laboratory officer and chief of pathology.
21. (1) The agents involved.
(2) Practices/techniques.
(3) Safety equipment (primary barriers).
(4) Facilities (secondary barriers).
22. They include BSL-1 practices plus limited access, biohazard warning signs, "sharps" precautions, biosafety manual defining any needed waste decontamination or medical surveillance practices.

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23. They include BSL-3 plus located in a separate building or isolated zone, dedicated supply and exhaust vacuum, and decontamination system, and other requirements as needed.
 24. A substance containing a viable microorganism, such as bacterium, virus, rickettsia, parasite, or fungus, that is known to or is reasonably believed to cause disease in humans or animals.
 25.
 - (1) Cutaneous form (collect vesicle swabs).
 - (2) Gastrointestinal form (collect stool or blood).
 - (3) Inhalation form (collect sputum or blood).
 26. A basic triple-packaging system is used with some additional specifications, labeling, and documentation requirements that are not used when shipping clinical specimens.
 27. These labels are required on the outer packaging: address label (higher-level laboratories address and phone number and shipper's name, address, and phone number), infectious substance label, and completed UN 2814 label.
 28.
 - (1) The requirements for rigorous packaging that will withstand rough handling and contain all liquid materials within the package without leakage to the outside.
 - (2) Appropriate labeling of the package with infectious substance symbol, biohazard symbol, and other labels to alert the workers in the transportation chain to the hazards of the package.
 - (3) Documentation of the hazardous contents of the package should such information be required in an emergency situation.
 - (4) Training of workers in the transportation chain to familiarize them with the hazardous contents, enabling them to properly respond to emergency situations.
 29. Your laboratory officer, the AFMS Web site, the Center for Clinical Laboratory Medicine at the Armed Forces Institute of Pathology (AFIP), or the CDC Web site.
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Unit Review Exercises

Note to Student: Consider all choices carefully, select the *best* answer to each question, and *circle* the corresponding letter. When you have completed all unit review exercises, transfer your answers to ECI (AFIADL) Form 34, Field Scoring Answer Sheet.

Do not return your answer sheet to AFIADL.

96. (030) To “rule-in and refer,” work at a BSL-3, and perform rapid identification on biological agents defines the scope of responsibilities of which LRN laboratory level?
 - a. Level A.
 - b. Level B.
 - c. Level C.
 - d. Level D.
97. (030) The use of clinical data and standard microbiology tests to decide which specimens and isolates are to be forwarded to one of the high-level biocontainment laboratories describes which of the LRN levels?
 - a. Level A.
 - b. Level B.
 - c. Level C.
 - d. Level D.

98. (030) Which of the LRN laboratory levels are designed to have the highest level of agent containment and have the expertise in the diagnosis of rare and dangerous biological agents?
- a. Level A.
 - b. Level B.
 - c. Level C.
 - d. Level D.
99. (030) Which CDC category of biological agents do we define as “moderately easy to disseminate and causing moderate morbidity and low mortality”?
- a. Category A.
 - b. Category B.
 - c. Category C.
 - d. Category D.
100. (030) The first one to be notified if your laboratory has presumptively identified a biological agent would be the
- a. chief of pathology.
 - b. MTF commander.
 - c. FBI.
 - d. CDC.

**When you complete this course, please complete the student survey on the Internet at this URL:
http://www.maxwell.af.mil/au/afiadl/operation/survey_fr.htm.**

Appendix A. The Periodic Table of Elements

Periodic Table of the Elements

Periodic Table of the Elements

I A		II A		III A		IV A		V A		VI A		VII A		VIII A	
1	1s ¹	2	1s ²												
H 1.00794		He 4.002602													
3	(He) 2s ¹	4	(He) 2s ²												
Li 6.941		Be 9.012182													
11	(Ne) 3s ¹	12	(Ne) 3s ²												
Na 22.989768		Mg 24.3050													
19	(Ar) 4s ¹	20	(Ar) 4s ²												
K 39.0983		Ca 40.078													
37	(Kr) 5s ¹	38	(Kr) 5s ²												
Rb 85.4678		Sr 87.62													
55	(Xe) 6s ¹	56	(Xe) 6s ²												
Cs 132.90543		Ba 137.327													
87	(Rn) 7s ¹	88	(Rn) 7s ²												
Fr (223.0197) ^a		Ra (226.0254) ^a													
		Ac [†] (227.0278) ^a													
		? ^b (261) ^a													
		Hs ^b (262.114) ^a													
				a Value in parentheses denotes mass number of most stable known isotope. Name and symbols are not officially accepted. Kurchatovium, Ku, has been proposed by Russian investigators and rutherfordium, Rf.											

III A		IV A		V A		VI A		VII A		VIII A	
5	(He) 2s ² 2p ¹	6	(He) 2s ² 2p ²	7	(He) 2s ² 2p ³	8	(He) 2s ² 2p ⁴	9	(He) 2s ² 2p ⁵	10	(He) 2s ² 2p ⁶
B 10.811		C 12.011		N 14.00674		O 15.9994		F 18.9984032		Ne 20.1797	
13	(Ne) 3s ² 3p ¹	14	(Ne) 3s ² 3p ²	15	(Ne) 3s ² 3p ³	16	(Ne) 3s ² 3p ⁴	17	(Ne) 3s ² 3p ⁵	18	(Ne) 3s ² 3p ⁶
Al 26.981539		Si 28.0855		P 30.973762		S 32.066		Cl 35.4527		Ar 39.948	
31	(Ar) 3d ¹⁰ 4s ²	32	(Ar) 3d ¹⁰ 4s ²	33	(Ar) 3d ¹⁰ 4s ²	34	(Ar) 3d ¹⁰ 4s ²	35	(Ar) 3d ¹⁰ 4s ²	36	(Ar) 3d ¹⁰ 4s ²
Ga 69.723		Ge 72.61		As 74.92159		Se 78.96		Br 79.904		Kr 83.80	
49	(Kr) 4d ¹⁰ 5s ²	50	(Kr) 4d ¹⁰ 5s ²	51	(Kr) 4d ¹⁰ 5s ²	52	(Kr) 4d ¹⁰ 5s ²	53	(Kr) 4d ¹⁰ 5s ²	54	(Kr) 4d ¹⁰ 5s ²
In 114.818		Sn 118.710		Sb 121.757		Te 127.60		I 126.90447		Xe 131.29	
81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴ 5d ¹⁰	84	(Xe) 4f ¹⁴ 5d ¹⁰	85	(Xe) 4f ¹⁴ 5d ¹⁰	86	(Xe) 4f ¹⁴ 5d ¹⁰
Tl 204.3833		Pb 207.2		Bi 208.98037		Po 209.9828 ^a		At 209.9871 ^a		Rn 222.0176 ^a	
201	(Hg) 6s ²	202	(Hg) 6s ²	203	(Hg) 6s ²	204	(Hg) 6s ²	205	(Hg) 6s ²	206	(Hg) 6s ²
Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		Br 79.904		Kr 83.80	
79	(Xe) 4f ¹⁴ 5d ¹⁰	80	(Xe) 4f ¹⁴ 5d ¹⁰	81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴ 5d ¹⁰	84	(Xe) 4f ¹⁴ 5d ¹⁰
Hg 200.59		Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		In 114.818	
112	(Xe) 4f ¹⁴ 5d ¹⁰	113	(Xe) 4f ¹⁴ 5d ¹⁰	114	(Xe) 4f ¹⁴ 5d ¹⁰	115	(Xe) 4f ¹⁴ 5d ¹⁰	116	(Xe) 4f ¹⁴ 5d ¹⁰	117	(Xe) 4f ¹⁴ 5d ¹⁰
Zn 65.39		Cu 63.546		Ni 58.6934		Co 58.93320		Fe 55.847		Mn 54.93805	
29	(Ar) 3d ¹⁰ 4s ¹	30	(Ar) 3d ¹⁰ 4s ¹	31	(Ar) 3d ¹⁰ 4s ¹	32	(Ar) 3d ¹⁰ 4s ¹	33	(Ar) 3d ¹⁰ 4s ¹	34	(Ar) 3d ¹⁰ 4s ¹
Ga 69.723		Ge 72.61		As 74.92159		Se 78.96		Br 79.904		Kr 83.80	
49	(Kr) 4d ¹⁰ 5s ²	50	(Kr) 4d ¹⁰ 5s ²	51	(Kr) 4d ¹⁰ 5s ²	52	(Kr) 4d ¹⁰ 5s ²	53	(Kr) 4d ¹⁰ 5s ²	54	(Kr) 4d ¹⁰ 5s ²
In 114.818		Sn 118.710		Sb 121.757		Te 127.60		I 126.90447		Xe 131.29	
81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴ 5d ¹⁰	84	(Xe) 4f ¹⁴ 5d ¹⁰	85	(Xe) 4f ¹⁴ 5d ¹⁰	86	(Xe) 4f ¹⁴ 5d ¹⁰
Tl 204.3833		Pb 207.2		Bi 208.98037		Po 209.9828 ^a		At 209.9871 ^a		Rn 222.0176 ^a	
201	(Hg) 6s ²	202	(Hg) 6s ²	203	(Hg) 6s ²	204	(Hg) 6s ²	205	(Hg) 6s ²	206	(Hg) 6s ²
Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		Br 79.904		Kr 83.80	
79	(Xe) 4f ¹⁴ 5d ¹⁰	80	(Xe) 4f ¹⁴ 5d ¹⁰	81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴ 5d ¹⁰	84	(Xe) 4f ¹⁴ 5d ¹⁰
Hg 200.59		Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		In 114.818	
112	(Xe) 4f ¹⁴ 5d ¹⁰	113	(Xe) 4f ¹⁴ 5d ¹⁰	114	(Xe) 4f ¹⁴ 5d ¹⁰	115	(Xe) 4f ¹⁴ 5d ¹⁰	116	(Xe) 4f ¹⁴ 5d ¹⁰	117	(Xe) 4f ¹⁴ 5d ¹⁰
Zn 65.39		Cu 63.546		Ni 58.6934		Co 58.93320		Fe 55.847		Mn 54.93805	
29	(Ar) 3d ¹⁰ 4s ¹	30	(Ar) 3d ¹⁰ 4s ¹	31	(Ar) 3d ¹⁰ 4s ¹	32	(Ar) 3d ¹⁰ 4s ¹	33	(Ar) 3d ¹⁰ 4s ¹	34	(Ar) 3d ¹⁰ 4s ¹
Ga 69.723		Ge 72.61		As 74.92159		Se 78.96		Br 79.904		Kr 83.80	
49	(Kr) 4d ¹⁰ 5s ²	50	(Kr) 4d ¹⁰ 5s ²	51	(Kr) 4d ¹⁰ 5s ²	52	(Kr) 4d ¹⁰ 5s ²	53	(Kr) 4d ¹⁰ 5s ²	54	(Kr) 4d ¹⁰ 5s ²
In 114.818		Sn 118.710		Sb 121.757		Te 127.60		I 126.90447		Xe 131.29	
81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴ 5d ¹⁰	84	(Xe) 4f ¹⁴ 5d ¹⁰	85	(Xe) 4f ¹⁴ 5d ¹⁰	86	(Xe) 4f ¹⁴ 5d ¹⁰
Tl 204.3833		Pb 207.2		Bi 208.98037		Po 209.9828 ^a		At 209.9871 ^a		Rn 222.0176 ^a	
201	(Hg) 6s ²	202	(Hg) 6s ²	203	(Hg) 6s ²	204	(Hg) 6s ²	205	(Hg) 6s ²	206	(Hg) 6s ²
Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		Br 79.904		Kr 83.80	
79	(Xe) 4f ¹⁴ 5d ¹⁰	80	(Xe) 4f ¹⁴ 5d ¹⁰	81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴ 5d ¹⁰	84	(Xe) 4f ¹⁴ 5d ¹⁰
Hg 200.59		Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		In 114.818	
112	(Xe) 4f ¹⁴ 5d ¹⁰	113	(Xe) 4f ¹⁴ 5d ¹⁰	114	(Xe) 4f ¹⁴ 5d ¹⁰	115	(Xe) 4f ¹⁴ 5d ¹⁰	116	(Xe) 4f ¹⁴ 5d ¹⁰	117	(Xe) 4f ¹⁴ 5d ¹⁰
Zn 65.39		Cu 63.546		Ni 58.6934		Co 58.93320		Fe 55.847		Mn 54.93805	
29	(Ar) 3d ¹⁰ 4s ¹	30	(Ar) 3d ¹⁰ 4s ¹	31	(Ar) 3d ¹⁰ 4s ¹	32	(Ar) 3d ¹⁰ 4s ¹	33	(Ar) 3d ¹⁰ 4s ¹	34	(Ar) 3d ¹⁰ 4s ¹
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49	(Kr) 4d ¹⁰ 5s ²	50	(Kr) 4d ¹⁰ 5s ²	51	(Kr) 4d ¹⁰ 5s ²	52	(Kr) 4d ¹⁰ 5s ²	53	(Kr) 4d ¹⁰ 5s ²	54	(Kr) 4d ¹⁰ 5s ²
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Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		Br 79.904		Kr 83.80	
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Hg 200.59		Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		In 114.818	
112	(Xe) 4f ¹⁴ 5d ¹⁰	113	(Xe) 4f ¹⁴ 5d ¹⁰	114	(Xe) 4f ¹⁴ 5d ¹⁰	115	(Xe) 4f ¹⁴ 5d ¹⁰	116	(Xe) 4f ¹⁴ 5d ¹⁰	117	(Xe) 4f ¹⁴ 5d ¹⁰
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Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		Br 79.904		Kr 83.80	
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Hg 200.59		Au 196.96654		Pt 195.08		Ag 107.8682		Cd 112.411		In 114.818	
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Ga 69.723		Ge 72.61		As 74.92159		Se 78.96		Br 79.904		Kr 83.80	
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In 114.818		Sn 118.710		Sb 121.757		Te 127.60		I 126.90447		Xe 131.29	
81	(Xe) 4f ¹⁴ 5d ¹⁰	82	(Xe) 4f ¹⁴ 5d ¹⁰	83	(Xe) 4f ¹⁴						

^a Value in parentheses denotes mass number of most stable known isotope.
^b Name and symbols are not officially accepted. Kurchatovium, Ku, has been proposed by Russian investigators and rutherfordium, Rf, by American investigators for element 104.

Atomic weights have been updated according to De Laeter, J.R., Heumann, K.G., Barber, R.C., et. al.: Atomic weights of the elements, 1991. Pure and Appl. Chem., 64(10): 1519-1534, 1992.

58	Ce	59	Pr	60	Nd	61	Pm	62	Sm	63	Eu	64	Gd	65	Tb	66	Dy	67	Ho	68	Er	69	Tm	70	Yb	71	Lu
140.115	140.90765	144.24	144.9127 ^a	150.36	151.965	157.25	158.92534	162.50	164.93032	167.26	168.93421	173.04	174.967	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	(Xe) 4f ¹ 6s ²	
90	Th	91	Pa	92	U	93	Np	94	Pu	95	Am	96	Cm	97	Bk	98	Cf	99	Es	100	Fm	101	Md	102	No	103	Lr
232.0381	(231.03588) [†]	238.0508	(237.0482) [†]	238.02891 [†]	238.02891 [†]	237.0482 [†]	237.0482 [†]	239.05216 [†]	239.05216 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	237.0482 [†]	

* Lanthanoid Series

† Actinoid Series

Student Notes

Glossary

Terms

- absorbance**—When applied to light, the characteristic of a substance to *not* allow light to travel through.
- accuracy**—An agreement between the best estimate of a quantity and its true value.
- adsorb**—To accumulate on the surface of a solid.
- alternative site testing**—Laboratory testing that is performed under MTF jurisdiction but outside the central laboratory environment.
- atom**—The smallest particle of an element capable of taking part in a chemical change.
- Beer's law**—A principle which states that if a reagent is standardized, the amount of color produced in a reaction will be directly proportional to the amount of the substance being measured.
- biomedical repair**—Technicians, usually working directly for a hospital, trained in the repair and maintenance of hospital equipment.
- bonding**—The process by which compounds are formed when atoms of differing elements share their electrons.
- calibration material**—A material or device of known or assigned quantitative and/or assigned qualitative characteristics (e.g., concentration, activity, intensity, and reactivity) used to calibrate, graduate, or adjust a measurement procedure or to compare the response obtained with the response of a test specimen and/or samples.
- calibration**—The “locking in” of a standard value on an instrument.
- certified reference material (CRM)**—Reference material, accompanied by certificate, one or more of whose property values are certified by a procedure which establishes tractability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.
- chromatographic grade**—Minimum purity of greater than 99% as determined by gas chromatography, no single impurity exceeding 0.2%.
- chromatography**—A term used to describe the separation of substances in a common solvent so that each may be identified separately.
- CLIA '88**—Clinical Laboratory Improvement Amendment of 1988. Set of federal regulations that govern the operations of clinical laboratories and performance of diagnostic testing.
- clinical laboratory**—A laboratory for measurement and examination of materials derived from the human body for the purpose of providing information on diagnosis, monitoring prevention, or treatment of disease.
- control material (CM)**—A device, solution, lyophilized preparation, or pool of collected human or animal specimen, or artificially derived material, intended for use in the quality control process (and is not used for calibration purposes in the same process in which they are used as controls).
- cornea**—Outer lens of the eye.
- cumulative sum chart**—A control chart on which the plotted value is the cumulative sum of deviations of successive samples from a target value. The ordinate of each plotted point represents the algebraic sum of the previous ordinate and the most recent deviations from the

target. See **quality control chart/graph**.

electron—A particle with a negative charge of one (–1), and a mass of only 1/1846 that of a proton.

electrophoresis—A separation technique using electrical current rather than mechanical means.

equilibrium—Deals with solutions; the process of obtaining and maintaining a balance between two solutions of differing concentrations.

equivalent weight—The molecular weight of a substance divided by its total positive or negative valence.

factory service—Technicians, usually working for a specific company, contracted to service and repair specific pieces of laboratory equipment.

file—A collection of related records that are treated as a unit.

fluorophore—A fluorescent substance used as a tag or tracer in fluorescent immunoassay procedures.

indigenous—Native, or not exotic.

interferent—An NCCLS term referring to components of samples, other than the analyte, that alter the final result and, in turn, affect the accuracy of the analytical method.

isotope—Atoms of the same element with different atomic masses (caused by differing numbers of neutrons).

laboratory—A place equipped for performing experimental work or investigative procedures, for the preparation of drugs, chemicals, etc.

Lambert's law—A principle which states that the absorbance of a solution will increase exponentially when you increase the light path.

Levy Jennings graph—Allows review of daily control values versus the mean performance of a peer group. See **quality control chart/graph**.

ligand—The term used to represent the analyte being measured in immunoassay procedures.

mean—The average value of a group of measurements.

medical—Pertaining to medicine or to the treatment of diseases; pertaining to medicine as opposed to surgery.

method correlation—A process used to compare test instruments or methods to see if they will yield similar results under the same conditions.

molarity—One gram molecular weight of a substance in one liter of solution.

neutralization—The process that occurs when acids and bases come into contact with each other. Salt and water are the normal by-products of this reaction.

neutron—A particle with a mass of one AMU, but no electrical charge (neutral).

normality—The gram equivalent weight of a substance in one liter of solution.

orbital—A spherical cloud in which electrons circle the nucleus of an atom.

percutaneous—Performed through the skin, the removal of tissue for biopsy accomplished by a needle.

point-of-care testing (POCT)—Diagnostic testing that is performed near or at the site of patient care. If performed at an MTF, it can also be called alternative site testing.

practical grade—Contains some impurities but is usually adequate for most organic preparations. However, it should not be used in clinical chemical analysis without prior purification.

precision—The reproducibility or the variation of repeat measurements of the same analyte.

primary standard—A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

proficiency testing—Samples tested that have been provided by an external organization to assess the quality of analysis in your laboratory.

proton—A particle with a positive charge of one (+1) and a mass of one AMU.

quality assurance (improvement)—A well-defined, organized program designed to enhance patient care through the ongoing objective assessment of important aspects of patient care and the correction of identified problems.

quality control (QC)—Procedures designed to ensure accurate and reliable performance of testing procedures by analyzing, monitoring, and taking corrective action, if necessary.

quality control chart/graph

- **Cumulative Sum Chart**—A control chart on which the plotted value is the cumulative sum of deviations of successive samples from a target value. The ordinate of each plotted point represents the algebraic sum of the previous ordinate and the most recent deviations from the target.
- **Levy Jennings Graph**—Allows review of daily control values versus the mean performance of a peer group.
- **Youden Plot**—Allows comparison of the relationship of each level's mean to the group performance.

quality—An attribute, a character trait, or degree or grade of excellence.

random errors—The result of chance, they normally do not affect an entire run or batch of samples, and may *not* be detected by testing control specimens. Random errors introduce increased variability into a procedure.

range—The difference between the smallest and largest values in a data group.

reagent grade—Certified to contain impurities below levels established by the Committee on Analytical Reagents of the ACS.

reference materials (RM)—A material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

reference standard—A standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

secondary calibrator—A substance or device that is based on a reference preparation or in which the analyte concentration or other quantity has been determined by a formal analytical procedure of stated reliability.

secondary standard—A standard whose value is assigned by comparison with a primary standard of the same quantity.

shift—All results now appear on one side or the other of the mean.

significant figure—A measured number which all of the number of digits are known for certain.

slurry—A thin mixture of a liquid, especially water, and any of several finely divided substances, such as cement, plaster of paris, or clay particles.

specific gravity—A term used to express the concentration of particles in a solution compared to that of pure water.

spectrophotometer—A piece of laboratory equipment that has programmable wavelength settings, used to measure the transmittance or absorbance of light.

spectroscopic grade—Spectrally pure in the visible, ultraviolet, and near- and mid-infrared ranges.

standard deviation (SD)—The square root of the variance.

standard—Something considered by an authority or by general consent as a basis of comparison or a material against which other materials can be compared.

STAT lab—A section of the laboratory designated to process emergency requests. Turnaround of results is much faster than “routine” lab testing.

surfactant—A substance that reduces the surface tension of water, creating a lubricating effect.

systematic errors—Affect all results within the run or batch and can usually be detected by testing control specimens. A systematic error introduces a bias (change of mean) into a procedure.

tertiary standard—A material, the analyte concentration of which has been value assigned by reference to a secondary standard.

total quality management (TQM)—A management philosophy that encompasses an expansion of continuous quality management. TQM emphasizes team or institutional performance rather than individual or department performance.

transmission—When applied to light, the ability of a substance to allow light to pass through.

trend—A series of control values that continue to move in the same direction (increase or decrease) over a period of time.

Type I water—Used in test methods requiring minimal interference and maximum precision and accuracy.

Type II water—Used for general laboratory testing not requiring Type I water.

Type III water—Used for glassware washing.

ultrapure reagents—Are required for gas chromatography, high-performance liquid chromatography (HPLC), fluorometry, and trace metal analyses and are termed “Spectrograde,” “Nanograde,” and “HPLC pure.”

USP grade and NF grade—Meets standards established by the US Pharmacopeia (USP) or National Formulary (NF) but they may contain impurities that have not been identified or tested for.

vesicle—A small circumscribed epidermal elevation, usually containing a clear fluid.

viscosity—A physical property of a solution, defined as the resistance of a fluid to flow.

waived testing—A CLIA test complexity category that includes tests that have an insignificant risk of an erroneous result. Tests that have been approved for home use by the Food and Drug Administration (FDA).

wavelength—Used to measure light, the distance from the crest of one wave of a light beam to the crest of the next wave in the same beam.

working standard—A standard that is used routinely to calibrate or check material measures (values), measuring instruments, or reference materials.

Youden plot—Allows comparison of the relationship of each level's mean to the group performance.
See **quality control chart/graph**.

Abbreviations, Acronyms, and Symbols

% T	percent transmittance (a measurement of light)
≈	mathematical symbol for approximately
μl	microliter
ACS	American Chemical Society
AFEPL	Air Force Electronic Publications Library
AFHCP	Air Force Hazard Communication Program
AFI	Air Force instruction
AFIP	Armed Forces Institute of Pathology
AFMAN	Air Force manual
AFOSH	Air Force Occupational and Environmental Safety, Fire Protection, and Health
AFPD	Air Force policy directive
AFSC	Air Force specialty code
AIDS	acquired immune deficiency syndrome
AMU	atomic mass unit
APHL	Association of Public Health Laboratories
APT	accurate and precise technology
ASCP	American Society of Clinical Pathologists
BAP	5% sheep blood agar
BEE	Bioenvironmental Engineers
BES	Bioenvironmental Engineering Services
BSC	biosafety cabinet
BSL	biosafety level
BT	bioterrorism
C	Celsius (a type of temperature)
CAP	College of American Pathologists
CCLM	Center for Clinical Laboratory Medicine
CDC	Centers for Disease Control and Prevention
CDC	career development course
CFETP	career field education and training plan
CFR	Code of Federal Regulations
CFU/ml	colony forming units per milliliter
CHOC	chocolate agar
CHP	chemical hygiene plan

CLIA '88	Clinical Laboratory Improvement Amendment of 1988
cm	centimeter
CM	control material
COLA	Commission on Office Laboratory Accreditation
COR	chief of an office of records
CPR	cardiopulmonary resuscitation
CPT	current procedural terminology
CRM	certified reference material
CV	coefficient of variation
DMAIC	define, measure, analyze, improve, and control
DNA	deoxyribonucleic acid
DOD	Department of Defense
DRMO	Defense Reutilization and Marketing Office
DRU	direct reporting unit
e	electron
ECOMS	Executive Committee of the Medical Staff
EDTA	ethylenediaminetetraacetic acid
EHS	Environmental Health Services
EIA	enzyme immunoassay
ELISA	enzyme-linked immunoabsorbant assay
EMB	eosin methylene blue agar
EMIT	enzyme multiplied immunoassay technique
EPILAB	Institute of Environmental Safety, Occupational Health, and Risk Analysis
FARM	functional area records manager
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FHCTP	Federal Hazard and Communication Training Program
FIA	fluorescent immunoassay
FOA	field operating agency
FOUO	for official use only
g	gram(s) (a metric unit of measure for weight)
GC	gas chromatography
GC/MS	gas chromatography/mass spectrometry
HAP	Hazard Abatement Plan

HBV	hepatitis B virus
HEPA	high-efficiency particulate air
HHSC	health hazard severity category
HICPAC	Hospital Infection Control Practices Advisory Committee
HIPAA	Healthcare Insurance Portability and Accountability Act of 1996
HIV	human immunodeficiency virus
HMIS	Hazardous Material Information System
HPLC	high-performance liquid chromatography
HQ USAF	Headquarters United States Air Force
HR	hazard report
IAW	in accordance with
ICC	Infection Control Committee
ICRF	Infection Control Review Function
ICSH	International Committee for Standardization in Hematology
ID	identification
ISE	ion selective electrode(s)
IUPAC	International Union of Pure and Applied Chemistry
IV	intravenous
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
kcal/g	kilocalories per gram (a unit to express energy)
L or l	liter (as in a liter of solution)
LAI	laboratory-acquired infection
LAN	local area network
LC	liquid chromatography
LOR	letter of reprimand
LRN	Laboratory Response Network
M	molar (as in a molar solution)
MAC	MacConkey agar
MAJCOM	major command
MEPRS	Medical Expense and Performance Reporting System
mg	milligram
mg/ml	milligrams per milliliter
MHS	Military Health Service
ml	milliliter (a metric unit of measure for volume)

mm	millimeter
MPC	mishap probability category
MPL	master publications library
MSDS	Material Safety Data Sheet
MTF	medical treatment facility
n	neutron
N	the number designation for the primary electron shells surrounding an atom
N	normal (as in a normal solution)
NCCLS	National Committee for Clinical Laboratory Standards
NCOIC	noncommissioned officer in charge
NF	National Formulary
NFPA	National Fire Protection Agency
NH	Notice of Hazard
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NLRN	National Laboratory Response Network
nm	nanometer (a unit of measurement for a light wavelength)
NRC	Nuclear Regulatory Commission
NRSCL	National Reference System for Clinical Laboratories
OEL	occupational exposure limit
OI	operating instruction
OIC	officer in charge
OJT	on-the-job training
OPR	office of primary responsibility
OSHA	Occupational Safety and Health Administration
p	proton
PAC	principal assigned characteristic
PAV	principal assigned value
PCV	packed cell value
PDSA	plan-do-study-act
PH	potential of hydrogen (unit used to measure the base or acidity of a solution)
PKU	phenylketonuria
pO₂	partial pressure of oxygen
POCT	point-of-care testing

PPE	personal protective equipment
ppm/b/t	parts per million/billion/trillion
PT	prothrombin time
PTT	partial thromboplastin time
QA	quality assurance
QAV	quality assistance visit
QC	quality control
QI	quality improvement
RAC	Risk Assessment Code
RBC	red blood cell
RIA	radioimmunoassay
RIMS	Records Information Management System
RM	reference material
RM	records manager
RNA	ribonucleic acid
RSO	radiation safety officer
RT	records technician
SAV	staff assistance visit
SD	standard deviation
SI	International System of Units (a scientific community system of measurement)
SPS	sodium polyanetholsulfonate
SRM	standard reference material
SSN	Social Security Number
STD	sexually transmitted disease
TLC	thin-layer chromatography
TO	technical order
TQM	total quality management
U/ml	units per milliliter
UCMJ	Uniform Code of Military Justice
UN	United Nations
USAMRIID	US Army Medical Research Institute of Infectious Diseases
USC	United States Code
USP	United States Pharmacopoeia
UV	ultraviolet

VC	volume, concentration
WBC	white blood cell
WWHCP	Workplace Written Hazard Communication Program

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National Committee for Clinical Laboratory Standards—Guidelines

<u>Title</u>	<u>Number</u>	<u>Date</u>
<i>Clinical Laboratory Safety; Approved Guideline</i>	GP17-A	September 1996
<i>Clinical Laboratory Technical Procedure Manuals—4th Edition; Approved Guideline</i>	GP2-A4	April 2002
<i>Point of Care in Vitro Diagnostic Testing; Approved Guideline</i>	AST2-A	June 1999
<i>Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture—4th Edition</i>	H4-A4	July 1991
<i>Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture—4th Edition</i>	H3-A4	July 1998
<i>Procedures for the Handling and Processing of Blood Specimens</i>	H18-A2	October 1999
<i>Terminology and Definitions for Use in NCCLS Documents—Third Edition; Approved Standard</i>	NRSCL8-A	November 1998

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