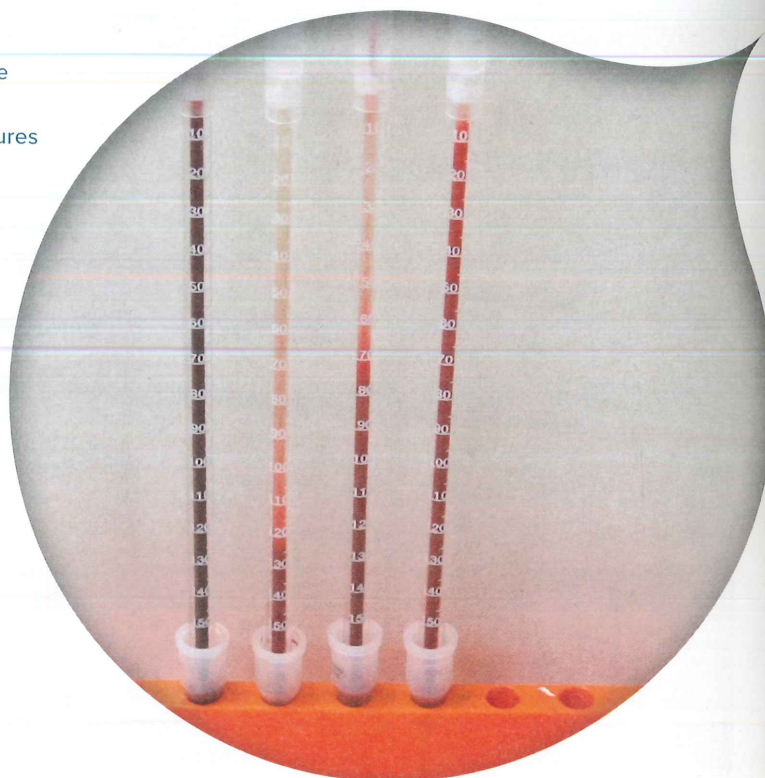


15

Waived Testing

essential terms

Certificate of Waiver	presumptive negative
Clinical Laboratory Improvement Advisory Committee (CLIAAC)	provider-performed microscopy procedures (PPMPs)
Clinical Laboratory Improvement Amendments (CLIA '88)	rapid diagnostic test (RDT)
dipstick	reagents
erythrocyte sedimentation rate (ESR)	rouleaux formation
glucose testing	standard operating procedures (SOPs)
hematocrit	strep screening
high complexity tests	urinalysis
human chorionic gonadotropin (hCG)	urine chemical screening
microhematocrit	urine pregnancy tests
moderate complexity tests	waived tests
packed cell volume (PCV)	
point-of-care testing (POCT)	



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Learning Outcomes

- 15.1** Differentiate among waived tests, moderate complexity tests, and high complexity tests.
- 15.2** Identify methods of performing an erythrocyte sedimentation rate.
- 15.3** Explain the procedure for performing a microhematocrit and the reasons why this test is performed.
- 15.4** Describe the general procedure for performing a rapid diagnostic test on blood for infectious diseases.
- 15.5** Describe the general procedure for performing a rapid diagnostic test for respiratory infections.
- 15.6** List the types of waived tests that are commonly performed on urine specimens.
- 15.7** Describe the waived procedure to test for fecal occult blood.
- 15.8** Explain the purpose of point-of-care testing.

Related NAACLS Competencies

- 4.3** Describe the types of patient specimens that are analyzed in the clinical laboratory.
- 4.6** Explain the importance of timed, fasting, and stat specimens, as related to specimen integrity and patient care.
- 5.1** Demonstrate knowledge of collection equipment, various types of additives used, special precautions necessary, and instances that can interfere in clinical analysis of blood constituents.
- 5.2** Identify the various types of additives used in blood collection, and explain the reasons for their use.
- 5.5** Describe substances that can interfere in clinical analysis of blood constituents and ways in which the phlebotomist can help to avoid these occurrences.
- 7.1** Demonstrate understanding of requisitioning, specimen transport, and specimen processing.
- 7.3** Instruct patients in the proper collection and preservation for non-blood specimens.

Introduction

With appropriate training, phlebotomists may perform specific tests known as waived testing in states that do not restrict them. Many tests are included on the ever-changing list of waived tests. Phlebotomists should be aware of the level of testing that they may be asked to perform and perform only tests that are waived. Waived testing procedures can be performed using kits that are available from a number of manufacturers. These kits include easy-to-follow instructions and most come with built-in controls. Healthcare employees in various clinical settings may perform these tests, which include (but are not limited to)

- erythrocyte sedimentation rate (ESR)
- fecal occult blood testing
- microhematocrit
- rapid diagnostic tests
- urine pregnancy testing
- urine chemical screening
- point-of-care testing (POCT)

Although phlebotomists do not typically perform these tests, in some settings, such as rural communities or other areas where laboratory personnel shortages exist, phlebotomists may be instructed on the performance of these tests. Phlebotomists must be aware that, in some states, such as California, licensure laws regulate waived testing, so phlebotomists may not be allowed to perform them.

15.1 Levels of Laboratory Testing

The 1988 **Clinical Laboratory Improvement Amendments (CLIA '88)** identified three levels of complexity for medical laboratory tests: waived tests, moderate complexity tests, and high complexity tests. Provider-performed microscopy was recognized and added to this law in 1997 as a subcategory at the moderate complexity level.

Testing Levels

High complexity tests are tests that require close attention to detail. These difficult tests have numerous steps and present challenges during the pre-examination, examination, and/or post-examination phases. Medical laboratory personnel are required to have specialized training and “substantial experience” to perform these procedures.

High complexity tests include those that require manual manipulation of highly complex equipment and **reagents** (lab test chemicals) and that require interpretation and troubleshooting skills. Manual DNA extraction procedures, intricate special staining procedures, and operation of complex analyzers that require detailed setup or operator interaction are included in this category.

Moderate complexity tests fall between waived (low complexity) and high complexity tests with respect to the difficulty of the test and the training required. Moderate complexity tests have a few procedural steps that are not highly complex but do require some formal training to perform. Depending on your level of training and place of employment, performing these tests may require direct supervision.

Moderate complexity tests include running automated instruments. These tests also require little manual manipulation of the specimen or reagents, with minimal interpretation and troubleshooting skills.

Healthcare providers perform **provider-performed microscopy procedures (PPMPs)** only for their own patients. PPMPs include

- direct wet mounts
- potassium hydroxide (KOH) preparations
- pinworm examinations
- fern tests
- post-coital qualitative
- urine sediment examinations
- nasal smears for granulocytes
- fecal leukocyte examinations
- qualitative semen evaluation

Waived tests are procedures that the Food and Drug Administration (FDA) has cleared for home use and for the laboratory that are simple to use, are easy to interpret, and produce accurate results. These tests usually do not produce false results. Other tests categorized as waived tests are those that “pose no reasonable risk of harm” if the test is performed incorrectly.

Performing waived testing does not require as much training as higher complexity tests and learning how to perform these tests can be done through on-the-job instruction. Learning to perform waived tests in an educational setting such as a phlebotomy or medical assisting training program ensures the personnel possess at least minimal knowledge about these tests along with the skills to perform them.

Various tests have been and continue to be developed that are waived tests. Each test comes with specific directions from the manufacturer which should be followed when performing the test. Some examples of waived tests include

- blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
- cardiac marker diagnostics
- cholesterol
- erythrocyte sedimentation rate—nonautomated
- fecal occult blood
- rapid diagnostic tests
- spun microhematocrit
- urine chemical screening
- urine pregnancy tests—visual color comparison tests

Regulatory Compliance

All laboratories, including hospitals, physician offices, and reference laboratories, must comply with CLIA '88 and apply for certification to perform tests of varying complexity. The different levels of certification include the following:

- A Certificate of Accreditation (COA) is awarded to laboratories that perform moderate and/or high complexity testing that meet the standards of a private not-for-profit accreditation program. These laboratories must be surveyed every other year.
- A Certificate of Compliance (COC) is awarded to laboratories that perform moderate and/or high complexity testing after inspectors find that the laboratory is in compliance with all applicable CLIA requirements. These laboratories are required to be surveyed every other year.

- A Certificate of Registration (COR) is granted to a laboratory that has applied for either COA or COC. COR enables the laboratory to perform moderate and/or high complexity testing until it has been inspected and verified to meet all requirements for COA or COC.
- A Certificate for Provider-Performed Microscopy Procedures may be granted to laboratories at facilities where physicians, midlevel practitioners, or dentists perform only certain microscopy procedures as described earlier in the section *Testing Levels*.
- A **Certificate of Waiver** may be granted to a laboratory that performs only waived tests. Inspections are not required unless there is a complaint about the laboratory.

Laboratories performing waived tests must apply to the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), and be approved for a Certificate of Waiver. Waived testing is performed at various types of healthcare facilities. At inpatient facilities, the clinical laboratory professionals provide oversight for quality of testing, regulatory compliance, method validation, accuracy checks, testing procedures, staff training, and technical support to the areas or units performing testing. Laboratories that function under a Certificate of Waiver must submit to random inspections and investigation, if indicated. Though waived tests are simple to perform and interpret, care must still be taken when performing them. Patient care decisions are often made based on the outcome of waived tests.

In order to help ensure quality testing procedures and reduce patient error, the **Clinical Laboratory Improvement Advisory Committee (CLIA)** has made several recommendations for good practice in a Certificate of Waiver laboratory. These recommendations include laboratory management considerations and testing procedures before, during, and after the test.

Laboratory Management and Personnel

Facilities performing laboratory testing must designate the person who will be responsible for laboratory supervision. This is usually a physician or someone with enough laboratory experience to make decisions about testing. In addition, it is important that all laboratory personnel adhere to the established laboratory guidelines, regulations, and requirements. These include the following:

- Follow all applicable federal, state, and local regulations.
- Perform waived tests only.
- Follow the manufacturer's instructions in the package insert.
- Do not make modifications to the instructions.
- Allow random inspections by authorized agencies, such as the CMS.
- Establish a laboratory safety plan that follows OSHA guidelines.
- Have a designated area that has adequate space and conditions.
- Have enough personnel in the lab and train them appropriately.
- Have written documentation of each test performed.

The person who is performing waived testing must follow **standard operating procedures (SOPs)** for each test performed. The testing personnel must pay close attention to pre-examination, examination, or post-examination steps in the testing process.

Before the Test—Pre-Examination

- Confirm written test orders.
- Establish a procedure for patient identification.
- Give patients pre-test instructions and determine whether they have followed these instructions.
- Collect specimens according to package insert instructions.
- Label specimens appropriately.
- Never use expired reagents or test kits.

During the Test—Examination

- Perform quality control testing as indicated in the package insert.
- Correct any problem discovered during quality control testing before testing patient specimens.
- Establish a policy for frequency of control testing.
- Carefully follow all test-timing instructions.
- Interpret test results as instructed in product inserts.
- Record test results according to your office policy.

After the Test—Post-Examination

- Report test results to the physician in a timely manner.
- Follow package insert recommendations for follow-up or confirmatory testing.
- Follow OSHA regulations for disposing of biohazardous waste.

To ensure the quality of testing, laboratories are also required to participate in quality assurance/assessment programs for each test they perform. Quality assurance and assessment are discussed in the chapter *Quality Essentials*.

Checkpoint Questions 15.1

1. What is a Certificate of Waiver and when is it needed?
2. What are PPMP tests? Who is allowed to perform them? Within what level of testing do PPMP tests fall?

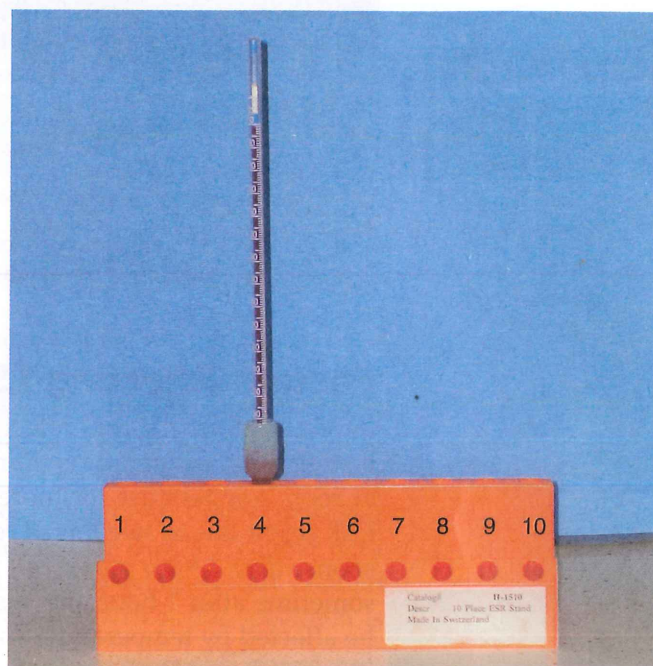
15.2 Erythrocyte Sedimentation Rate

The **erythrocyte sedimentation rate (ESR)** is the rate at which red blood cells (RBCs) settle in whole blood. What is actually measured is the distance, in millimeters, that the RBCs fall in 1 hour when allowed to settle in a calibrated tube. The ESR screens for the presence of any inflammatory process and is not diagnostic of any one condition. When inflammation is present, the number of plasma proteins, such as albumin and globulin, increases. An increase in these substances causes red blood cells to come closer together, which may result in **rouleaux formation** (RBCs sticking to each other). Several cells sticking together settle faster than a single RBC does. This results in an elevated sedimentation rate.

Several methods exist for performing the ESR, including Wintrobe, Westergren, and Modified Westergren. Manufacturers of kits for these methods have varying requirements for specimen tube type. Most require a lavender-topped EDTA tube, whereas others require a light-blue-topped tube or their own specialty tube, usually with a black stopper or top. ESR procedures are



A



B

Figure 15-1 (A) Transfer pipets—plastic, disposable droppers for transferring liquids. (B) An example of a Westergren method for erythrocyte sedimentation rate. The setup includes a vial that holds the diluted sample, a tube calibrated in millimeters, and a testing rack.

A: ©Lisa Eastman/Alamy Stock Photo RF; B: ©Leesa Whicker

best performed on fresh specimens less than 4 hours old, but they may be performed on refrigerated blood up to 12 hours old, depending on the test method. Always check the procedures and policies at your facility before performing laboratory tests.

A simple method for performing an ESR requires the following equipment (see Figure 15-1):

- Specimen transfer pipets
- ESR kit
- ESR vials containing a premeasured amount of diluent (usually 0.9% sodium chloride)
- Calibrated ESR tubes
- ESR testing rack

ESR Procedure

To perform an ESR procedure properly, follow the steps in Learn How 15-1. See Figures 15-2 and 15-3 for an example of one such ESR procedure.

Erythrocyte Sedimentation Rate Testing

1. Transfer the mixed blood from an appropriate specimen to the diluent vial and fill it to the mark on the vial (amounts vary by manufacturer).
2. Replace the vial cap and gently mix the blood with the diluent by inversion.
3. Insert a calibrated ESR tube through the vial cap and into the blood–diluent mixture; adjust the tube until the blood is even with the 0-mm mark.
4. Place the ESR tube in the testing rack (it should be absolutely level).

(continued)

Learn How 15-1

Erythrocyte Sedimentation Rate Testing (Continued)

5. Label the ESR tube or vial with the patient's identification.
6. Allow the blood to settle for 1 hour.
7. After 1 hour, read the level to which the red blood cells have fallen and record this information as millimeters per hour.
8. Consult the manufacturer's instructions for proper interpretation of the results. Normal values vary by method and may vary by sex.

Factors Affecting ESR Results

Several factors that may affect ESR results are time from collection to testing, testing time, temperature, tilting, and vibrations. If the specimen has been left at room temperature for more than 4 hours, it may have a lower-than-actual ESR result due to swelling of red blood cells over time. Reading the ESR result sooner than 1 hour may result in a falsely lower ESR, whereas reading the ESR sometime after 1 hour may result in a falsely higher ESR value. ESR tests can be affected by temperatures higher or lower than room temperature (68–77°F [20–25°C]) and by drafts or direct sunlight. Tilting the ESR tube, even slightly, will cause the red blood cells to settle faster, so it is important for the test rack to be absolutely level. Vibrations of the countertop on which the testing rack is placed will also cause the red blood cells to settle faster. To prevent this, the rack should not be placed on the same counter as centrifuges or other vibration-generating equipment.

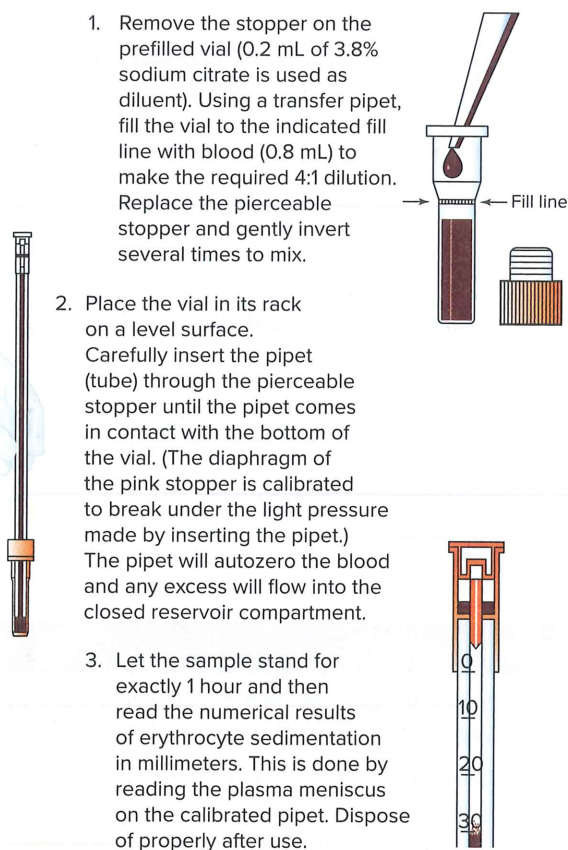


Figure 15-2 An example of one manufacturer's method for Westergren erythrocyte sedimentation rate (Sediplast ESR system).

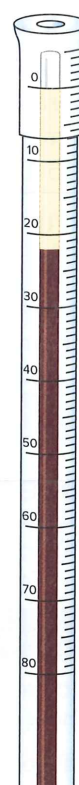


Figure 15-3 An example of erythrocyte sedimentation after 1 hour. The reading in this example is 22 millimeters.

1. Name three methods of performing waived ESR tests.
2. Why is it important to keep the ESR tube absolutely level during an ESR test?

Checkpoint Questions 15.2

15.3 Microhematocrit

A **hematocrit** (Hct or Crit) is used as a screening test for anemia and is measured as the **packed cell volume (PCV)** of red blood cells, or the percentage of red blood cells in whole blood. Figure 15-4 shows the separation of cells from plasma in a microhematocrit tube. A **microhematocrit** is a procedure for determining the hematocrit and requires only a small amount of blood. The microhematocrit procedure uses capillary tubes, which are narrow-diameter tubes with a red band around one end, indicating that they are coated with heparin (see Figure 15-5). Capillary tubes with a blue band do not contain any anticoagulant but may be used for a microhematocrit if the specimen is obtained from an EDTA tube or container.

Microhematocrit Testing

Microhematocrit testing can be performed directly on dermal (capillary) puncture blood or on blood that has been collected into a microcollection container or an evacuated tube. For tests performed directly from dermal (capillary) punctures, wipe away the first drop of blood with gauze. Using red-topped

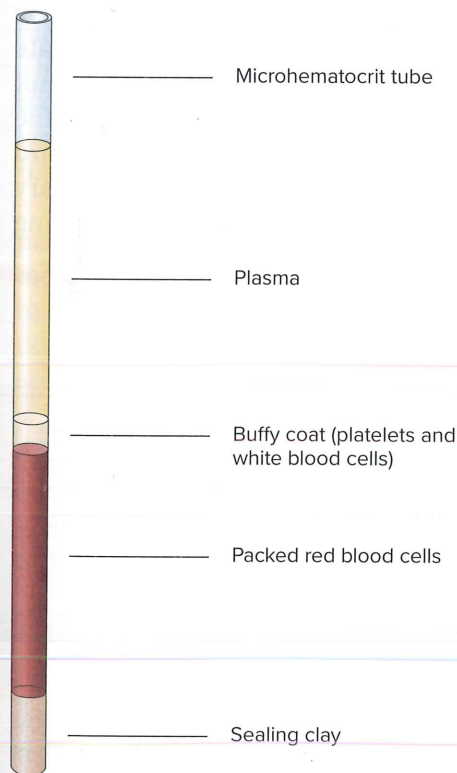


Figure 15-4 Hematocrit is the percentage of red blood cells in whole blood. This can be determined by measuring the percentage of packed red blood cells in a capillary tube that has been centrifuged.



Figure 15-5 Heparinized capillary tubes are used as microhematocrit tubes.
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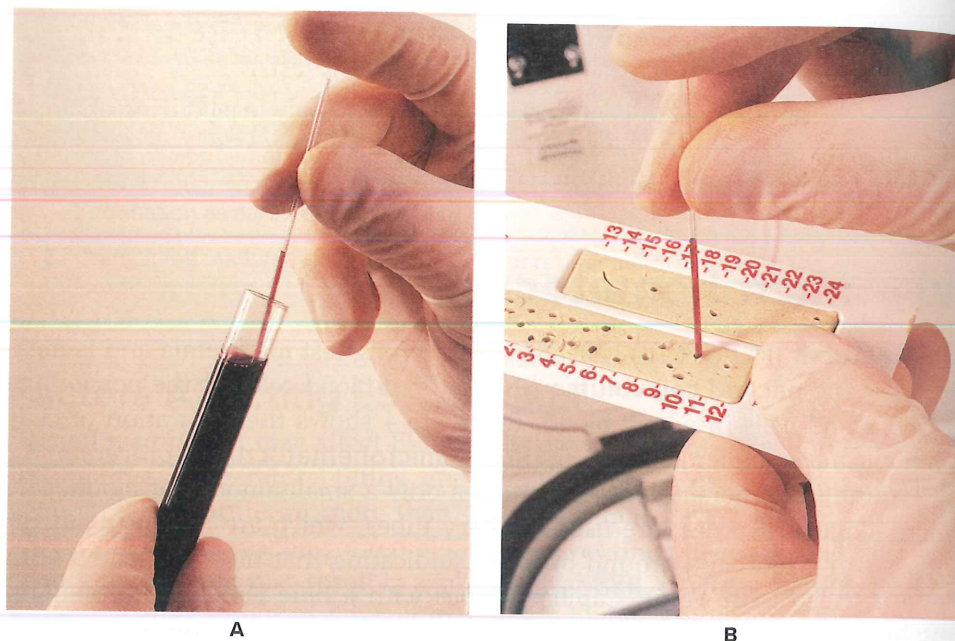


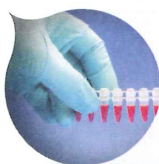
Figure 15-6 (A) A capillary tube may be filled from a pre-collected blood sample tube and (B) sealed with clay at the dry end.

A–B: ©Terry Wild Studio

capillary tubes, touch the tube to the edge of the blood drop without touching the skin. When filling capillary tubes from pre-collected tubes, tilt the specimen tube slightly and insert one end of the capillary tube (see Figure 15-6A).

Capillary tubes fill by capillary action, which occurs when blood flows freely into the tube without suction. Avoid allowing air to enter the tube, which may cause erroneous results. Fill two capillary tubes three-quarters full. The rate of filling can be increased or decreased by tilting the tube. However, do not remove the tip of the tube from the blood source with the tube lower than the blood. This will allow air to enter. Keep the tube horizontal or tilted upward during the filling process. Wipe excess blood off the outside of the capillary tubes with gauze. Hold the tube horizontally to prevent blood from leaking out of the tube.

Safety & Infection Control



Microhematocrit Tubes

Microhematocrit tubes/capillary tubes are very slender and when made of glass they are prone to breakage. A broken sharp edge can cause a tear in the phlebotomist's glove and skin, and consequently exposure to blood. Phlebotomists must use caution when handling these tubes. For safety, some brands of capillary tubes are made of plastic or glass that is wrapped in plastic.

Once a microhematocrit sample has been obtained, place a gloved finger over the dry end (the end of the capillary tube that was not used to collect the specimen) and hold it horizontal so no blood can spill out. Remove your finger from the dry end and seal it by embedding the clean end in a clay sealant designated for this use. Be careful not to lose any blood from the tube (see Figure 15-6B). Improper sealing of the capillary tube can cause blood to leak out, which may result in a decreased hematocrit reading, or no blood

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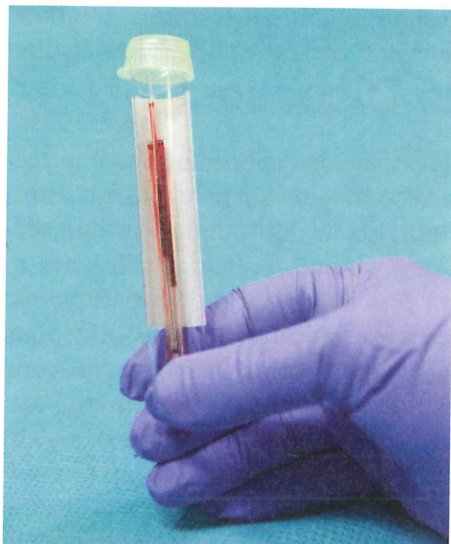


Figure 15-7 Filled capillary tubes may be transported in a larger tube with a label.

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Figure 15-8 Microhematocrit centrifuge. When loading a microhematocrit centrifuge, make sure that the tubes are balanced by placing them directly across from each other, with the sealed ends pointing outward.

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remaining in the tube. Some microhematocrit tubes are self-sealing and do not require this puttylike sealant. Follow manufacturer's directions to avoid tube breakage or blood leakage during centrifugation.

If microhematocrit tubes must be transported to the laboratory, place them in a larger tube for labeling and transport (see Figure 15-7). This is done because microhematocrit capillary tubes are fragile and too small to attach patient labels. Attempts to label these small capillary tubes can result in tube breakage, loss of the specimen, and potential injury to the phlebotomist.

A microhematocrit centrifuge (see Figure 15-8) is used to obtain packed red blood cells. To obtain these cells, balance the microhematocrit tubes in the microhematocrit centrifuge with the clay ends facing outward. Tighten the head cover on the centrifuge and close the lid. Turn on the microhematocrit centrifuge for the appropriate time, according to manufacturer's instructions.

The hematocrit is determined using a microhematocrit-reading device. Some microhematocrit centrifuges have this device built in. The bottom of the red blood cell layer is placed at the 0% mark and the scale is adjusted so that the top of the plasma layer is at the 100% mark. The hematocrit value is where the top of the red blood cell layer falls on the scale (see Figure 15-9). The two values of the microhematocrits (one from each tube) should match within 2%.

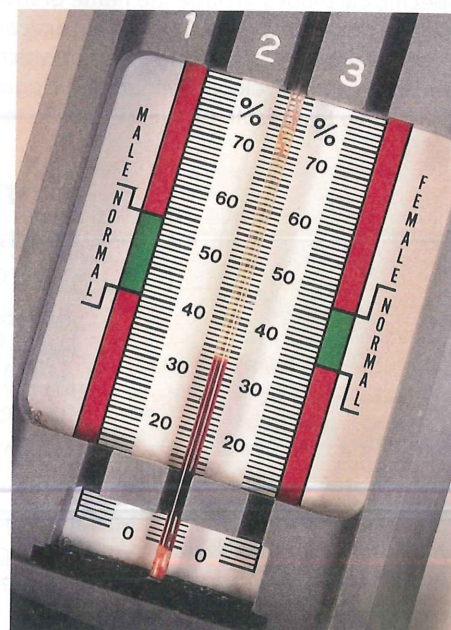


Figure 15-9 Compare the column of packed red blood cells in the capillary tube with the hematocrit scale and record the results. In this example, the hematocrit measures 33%.

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1. Briefly describe the proper way to obtain a microhematocrit specimen using dermal (capillary) puncture.
2. Why are microhematocrit tubes often transported inside larger tubes?

Checkpoint Questions 15.3

15.4 Rapid Diagnostic Tests (RDTs) on Blood for Infectious Diseases

Rapid diagnostic tests can be performed on various specimen types to test for pathogenic organisms or an immune response to such organisms. In a

relatively healthy individual, the immune system will react to infectious disease by producing antibodies to an antigen (protein) that is present on the pathogenic organism. RDTs that use blood to test for infectious diseases are designed to detect this antibody. Antigens specific to this antibody are incorporated onto the test region of a test cartridge or test strip, depending on the manufacturer. When a specimen is applied to a test cartridge, antibodies in the specimen that are specific to the immune response being tested are bound to the test membrane that contains the antigens for the organism. A developer reagent is added so that the reaction is visible as a band of color, as well as a band of color for a control reaction. If the antibodies are present in the specimen, the test band and the control band will both appear, yielding a positive result. If only the control band is present, the test result is negative. If there are no bands, or if only the test band appears, the test is invalid. See Figure 15-10. Some of the tests available by RDT methods include infectious mononucleosis, human immunodeficiency virus, and syphilis.

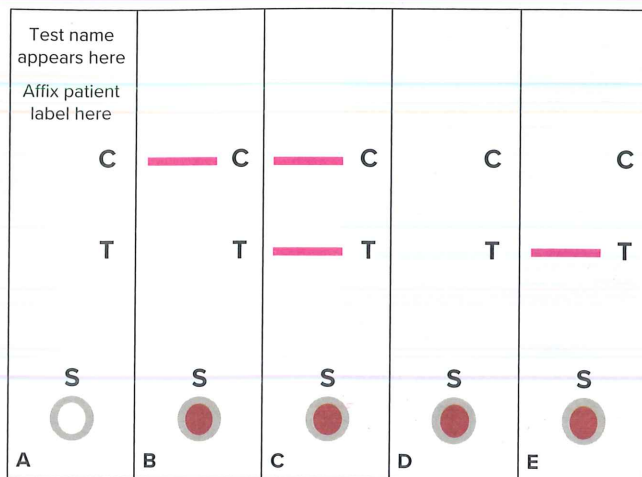


Figure 15-10 A generic Rapid Diagnostic Test cartridge to which a patient label should be affixed prior to testing. Specific cartridges include the name of the test for which it is use (for example, "MONO"). (A) Test cartridges have a control area, test area, and a well in which to apply the specimen and developer reagent. (B) Negative test result. (C) Positive test result. (D) and (E) Invalid test results.

Mono

Infectious mononucleosis (IM), also known as "mono," is a contagious disease caused mainly by the Epstein-Barr virus (EBV). Symptoms, exhibited mostly in young adults, can include extreme fatigue, fever, head and body aches, rash, sore throat, swollen lymph nodes in the neck and armpits, swollen liver and/or spleen. Symptoms of infectious mononucleosis can last for a few weeks to over six months. EBV and other viruses that cause IM are spread through bodily fluids (such as saliva). Patients with IM develop heterophile antibodies which may be present in a specimen of whole blood, serum or plasma. When a specimen is applied to a test cartridge IM specific heterophile antibodies are bound to the test membrane that contains IM antigens. A developer is added and the reactions are interpreted as described above.

HIV

Human immunodeficiency virus (HIV) attacks the body's immune system; and if left untreated, can lead to acquired immunodeficiency syndrome (AIDS). HIV occurs in three stages: Stage 1 Acute HIV infection, Stage 2 Chronic HIV infection, and Stage 3 AIDS. Currently there is no cure for HIV; so once infected, a person has HIV for life. Flu-like symptoms usually begin within 2 to 4 weeks after infection and may include chills and fever, night sweats, rash, muscle aches, sore throat and mouth ulcers, swollen lymph nodes, and fatigue. Other illnesses can exhibit these same symptoms and some people do not have any symptoms during the acute stage. Patients with HIV develop antibodies which may be present in a specimen of whole blood, serum or plasma. When a specimen is applied to a test cartridge, antibodies specific to HIV are bound

to the test membrane that contains HIV1 and HIV2 antigens. A developer is added and the reactions are interpreted as described above.

Syphilis

Syphilis caused by *Treponema pallidum*, a bacterium that is sexually transmitted (vaginal, anal, or oral sex) through direct contact with a syphilitic chancre. Pregnant women with the disease can transmit it to their fetus through the placenta or at birth to the newborn baby. Many people infected with syphilis do not have any symptoms and are unaware of their infection; and remain at risk for late complications if they are not treated, including internal organ damage and death as long as 10–30 years after initial infection. Patients with syphilis develop antibodies, which may be present in a specimen of whole blood, serum or plasma. When a specimen is applied to a test cartridge antibodies specific for *T. pallidum* are bound to the test membrane that contains *T. pallidum* antigens. A developer is added and the reactions are interpreted as described above.

1. What are produced in a healthy individual during an immune response toward an infectious disease?
2. Which microorganism causes infectious mononucleosis?



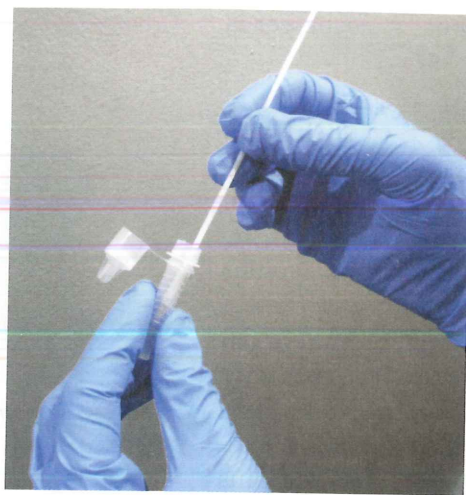
15.5 Rapid Diagnostic Tests (RDTs) for Respiratory Infections

RDTs for respiratory infections are tests to rapidly identify infectious diseases, such as influenza virus and corona virus. These tests provide a quick diagnosis so that patients infected by these viruses may be isolated to prevent spread of infection and to be treated immediately and appropriately. Rapid screening tests are designed to detect an antigen (protein) that is present on the pathogenic organism. Antibodies specific to this antigen are incorporated onto the test region of a test cartridge or test strip, depending on the manufacturer.

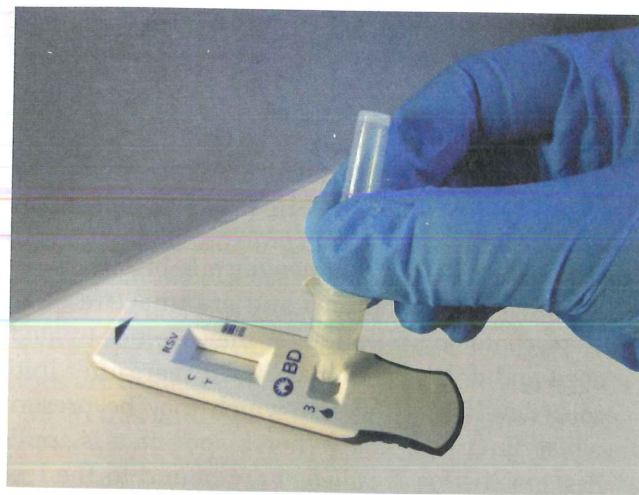
Depending on the organism, a swab from an appropriate source to detect the organism is collected. Organism antigens are extracted from the swab prior to testing and the extraction solution is applied to a test cartridge or test strip Figure 15-11. The antigens from a swab extraction react with the antibody particles in the cartridge, producing a visible line (usually red in color). A line in the test area indicates a positive result, while no line indicates a **presumptive negative** (no antigens are detected but the patient may still be infected with the organism). A control area is provided, which displays a line when the test is performed correctly. If no line is obtained in the control area, the test is invalid regardless of what the test area indicates (Figure 15-12). Each manufacturer has their own procedure and means of interpreting results. Depending on manufacturer and test, results may be available in 5 to 20 minutes. Be sure to follow the instructions specific for each kit.

Rapid FLU Testing

The flu is caused by various strains of the influenza virus and is a highly contagious, acute respiratory illness. A person with the flu may have any or all of the following symptoms: abrupt onset of fever, headache, malaise, myalgia,

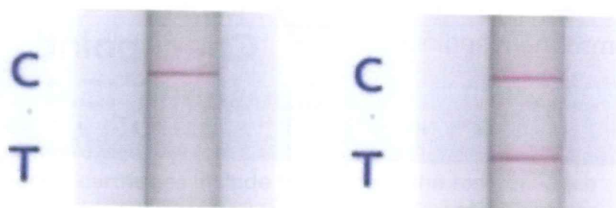


A

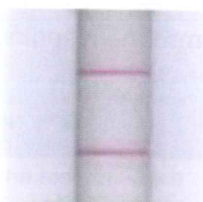


B

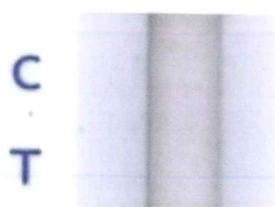
Figure 15-11 (A) Extracting antigens from a swab. (B) Applying extraction solution to test cartridge.
Lillian Mundt and Becton Dickinson



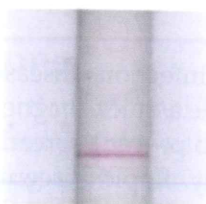
A. Negative



B. Positive



C. Invalid



D. Invalid

Figure 15-12 Interpretation of rapid test reactions
Lillian Mundt

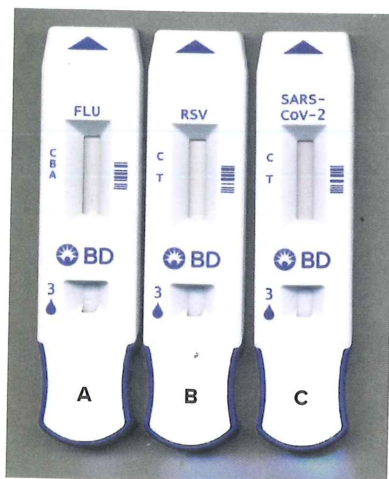


Figure 15-13 Test cartridges for rapid A. FLU; B. RSV; C. COVID-19
Becton Dickinson

nonproductive cough, rhinitis, and sore throat. A nasopharyngeal swab is collected (as described in the chapter “Collection of Non-blood Specimens”) and tested as described above. The rapid FLU test cartridge may include test areas for both influenza A and influenza B (Figure 15-13 A). A negative rapid FLU test is presumptive and if clinically indicated, a follow-up with alternative methods can be performed on a repeat nasopharyngeal swab collection placed in special media for PCR testing.

Rapid RSV Testing

Respiratory syncytial viruses (RSV) cause an “influenza-like” lower respiratory tract infection, affecting children under 5 years of age, as well as elderly patients, and immunocompromised patients. RSV is performed on a swab from patients suspected of having a viral respiratory infection. A nasopharyngeal swab is collected (as described in the chapter “Collection of Non-blood Specimens”) and tested as described above. See Figure 15-13B. Some kits may be approved for testing nasal swabs and nasopharyngeal aspirates or washes. A negative rapid RSV test is presumptive and if clinically indicated, a follow-up with alternative methods can be performed on a repeat nasopharyngeal swab collection placed in special media for PCR testing.

COVID-19 infections is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 are similar to other viral respiratory diseases and include cough, fever, and shortness of breath. A dual nares swab is collected (as described in the chapter “Collection of Non-blood Specimens”) and tested as described above. See Figure 15-13C. A negative rapid COVID-19 test is presumptive and if clinically indicated, a follow-up with alternate methods may be performed on a nasopharyngeal swab placed in special media for PCR testing.

Rapid COVID-19 Testing

COVID-19 infections is caused by the SARS-CoV-2 virus. The symptoms of COVID-19 are similar to other viral respiratory diseases and include cough, fever, and shortness of breath. A dual nares swab is collected (as described in the chapter “Collection of Non-blood Specimens”) and tested as described above. See Figure 15-13C. A negative rapid COVID-19 test is presumptive and if clinically indicated, a follow-up with alternate methods may be performed on a nasopharyngeal swab placed in special media for PCR testing.

Strep A Screening

Someone with a sore throat that presents suddenly, accompanied by fever but no cold symptoms (such as coughing or sneezing), may have strep throat. Strep screening is used to determine if the bacteria that causes strep throat, Group A *Streptococcus*, is present in the throat. This bacterium can also cause rheumatic fever and autoimmune disease if left undetected and untreated. A swab of the throat is collected (as described in the chapter “Collection of Non-blood Specimens”) and tested as described above (see Figure 15-14). A negative test is presumptive and is usually follow-uped with a throat culture.

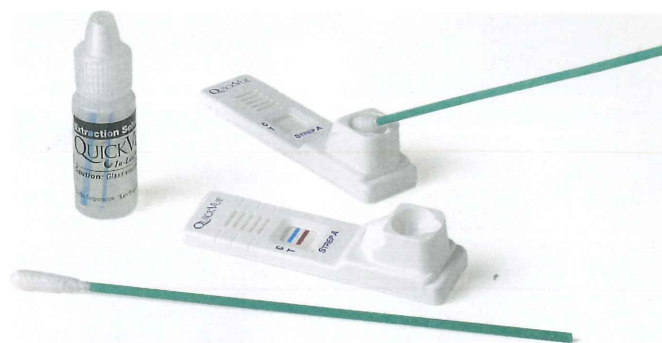


Figure 15-14 Testing devices used for rapid detection of Group A *Streptococcus* infections. Throat swab specimens are obtained and antigen is extracted; results can be reported in less than 10 minutes.

©Quidel Corporation

1. What type of bacteria causes strep throat?
2. Why is a rapid test result considered invalid if the control reaction is not present?

 **Checkpoint
Questions 15.5**

15.6 Urine Testing

Urine is one of the most accessible body fluids for analysis. Many different types of testing are performed on urine, including pregnancy tests and tests for various chemical and physical components.

Urine Pregnancy Testing

Urine pregnancy tests are performed on women to confirm or rule out pregnancy when pregnancy is suspected, as well as on women of childbearing age prior to invasive surgical procedures, such as gallbladder removal, cardiac surgery, or neurosurgery. During pregnancy, the placenta produces **human chorionic gonadotropin (hCG)**. This hormone is detectable in urine as early as 10 days after conception, rises during pregnancy, and usually returns to nondetectable levels in the third trimester.

Pregnancy test kits are available for home testing and waived testing laboratories. Procedures for pregnancy tests vary by manufacturer, so you must follow the instructions specific to the test kit used by your facility.

In general, the required number of drops of urine are deposited onto the testing device and allowed to react for the required amount of time. Some devices display a positive (+) or negative (–) symbol to indicate the presence or absence of detectable amounts of hCG. A built-in control indicator verifies that the test has been performed correctly (see Figure 15-15).

Urine Physical and Chemical Screening

Urine physical screening is performed by looking at the physical properties of the urine and evaluating the color and clarity. Urine colors range from colorless, straw, yellow, green, black, red, and orange with colorless to yellow being the most expected. The clarity of urine is typically seen as clear but may be hazy or cloudy when an abnormality such as a urinary tract infection is present. Both of these properties should be recorded.

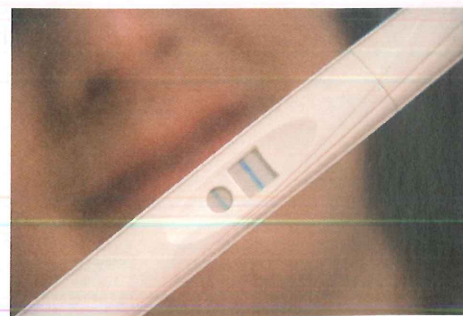


Figure 15-15 Test results from ready-purchased kits are easy to read. This pregnancy test gives a color reaction in the shape of a plus or minus sign. The test shown here is negative.

©Getty Images RF

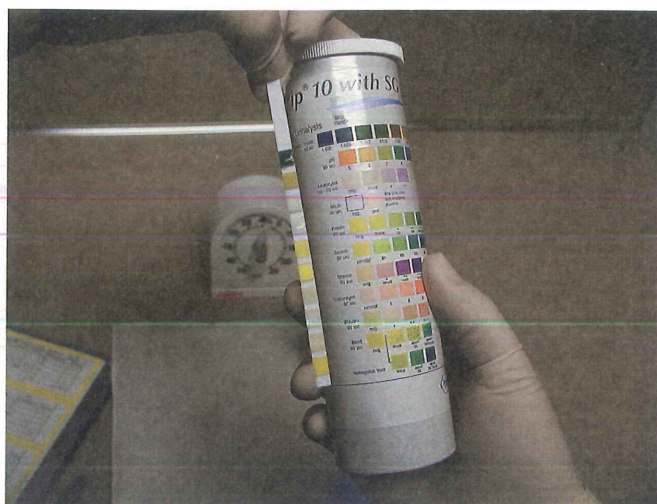


Figure 15-16 Reagent strips are dipped into the urine and then compared to colors on the reagent bottle to determine the results.

©Total Care Programming, Inc.

Urine chemical screening is part of a **urinalysis**, which is a tool used to evaluate substances found in urine. Urine tests can help determine the state of the human body if collected and analyzed properly. A complete urinalysis consists of three parts: a physical component, a chemical component, and a microscopic component. The physical component is the evaluation of color and clarity of the urine. The chemical component consists of measuring pH (acidity or alkalinity) and specific gravity (level of concentration) as well as detecting blood, bilirubin, glucose, ketones, leukocytes, protein, nitrites, and urobilinogen that may be abnormally present in urine. The microscopic component consists of pouring a well-mixed urine sample into a centrifuge tube, then spinning it down to obtain the sediment. The sediment is used to make a slide to view under a microscope to check for various cells, crystals, microorganisms, and urine casts (which are formed inside the kidney and are shaped like tiny tubes). Urine microscopic examination is *not* a waived procedure, and therefore is not performed by phlebotomists.

A phlebotomist who is properly trained may be asked to perform a urine chemical screening using a **dipstick test** (a plastic strip with reagent pads) (see Figure 15-16). These pads contain chemicals that react with a particular substance in urine and change color in precise ways. These changes indicate the presence of that substance and the amount or concentration of the substance in the urine specimen. For example, when a reagent strip is used to test for blood, the color on the strip, after it is allowed to react with the urine for the proper amount of time, will correspond to a specific concentration of blood or show that no blood is present in the urine. A small amount of blood may produce a green-blue color, whereas a large amount of blood will produce a dark blue color.

Urine Chemical Screening Procedure

To perform a urine chemical screening test, first verify the patient and collection information on the label to ensure that the correct specimen is being tested. Use all appropriate PPE (lab coat, gloves, and face shield) as required by your facility. Learn How 15-2 lists the steps to perform a urine chemical screening.

Learn How 15-2

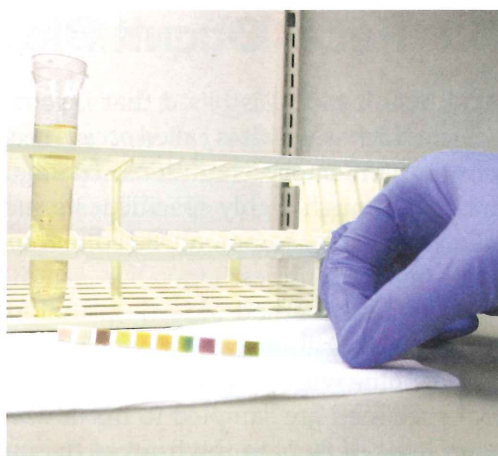
Urine Chemical Screening

1. Double-check that the specimen is correctly identified and matches the chart where you will record the results.
2. Allow the urine to come to room temperature, then mix the urine thoroughly.
3. Remove the reagent strip from the bottle and replace the cap.
4. Remove the cap from the urine container and dip the reagent strip into the urine, making sure that all the reagent pads come into contact with the urine.
5. Remove the reagent strip immediately by dragging it across the top of the container and/or touching the side edge to an absorbent material to prevent dripping. Never blot the tops of the pads on the strip and do not allow urine from one pad to run over onto another.
6. Begin timing immediately.
7. Compare the colors of the reagent pads to those of the color chart on the reagent strip bottle at the time designated by the manufacturer, to avoid erroneous results.
8. Record the test result for each chemical component in the patient's medical record.

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A



B



C

Figure 15-17 (A) Dip the urinalysis strip into the patient's urine. Be sure that all the reagent pads come in contact with the urine specimen. Promptly remove the reagent strip. (B) Remove any excess urine from the strip, but do not blot the strip. (C) Using the chart provided by the manufacturer and following the timing requirements, compare the color of each reagent pad located on the urinalysis strip to the chart. Record all results.

A–C: ©Lillian Mundt

Although the process is essentially the same for all reagent strip tests, there are variations in time intervals before reading results. Test reactions must be read at the designated time to avoid inaccurate results. Figure 15-17 shows the urine chemical screening procedure.

Several manufacturers produce urine reagent strips. Some of these strips are more sensitive to certain chemicals than others. You must choose the appropriate strip according to the chemical test requested. All reagent strips are used once and then discarded.

Follow the directions that come with the reagent strips used by your facility to ensure accurate results. For quality assurance, take these basic precautions:

- Keep strips in tightly closed containers in a cool, dry area.
- Never remove strips from the container until immediately before testing.
- Never touch the pads on the strip with your fingers or gloved hands.
- Examine strips for discoloration before use; discard discolored strips.
- Check the expiration date on the bottle; do not use strips that have expired.
- Use strips within the open expiration date of the container, usually 6 months.
- Every time you open a new supply of reagents, run control samples to check for proper operation. Write the date opened on the bottle.

Use the competency checklist *Urine Chemical Screening* at the end of this chapter to review and practice the procedure.

1. What hormone detected in the urine indicates that a woman is pregnant?
2. When performing urine chemistry tests using a reagent strip, why can't all the test results be read at the same time?

Checkpoint Questions 15.6

15.7 Fecal Occult Blood Testing

Fecal occult blood is blood that is found in the feces/stool and may not be visible, which is why it is called *occult*. Fecal occult blood may be a sign of infections, inflammatory conditions, trauma, ulcers, hemorrhoids, or colorectal cancer. Although highly specific tests such as the fecal immunohistochemical test are available, common waived methods for fecal blood testing may still be used by some facilities.

The waived method of testing stool for occult blood is done using a cardboard holder that contains a paper impregnated with guaiac, a chemical that will turn blue when blood is present (see Figure 15-18). Several portions of the stool specimen are sampled to maximize blood detection. For this test, apply a thin layer of stool to the front of the guaiac card as directed. After a 5 minute wait, add a few drops of hydrogen peroxide developer to the back of the card (always follow manufacturer's procedure). If a sufficient amount of hemoglobin is present, the guaiac paper will turn blue. False-negative results may occur if a very small amount of hemoglobin is present or if not enough stool was applied. False-positive results may occur if another type of peroxidase or pseudoperoxidase (enzyme present in some foods) is present. In most cases, the physician will order fecal occult blood "times three," requiring that three different stool specimens be collected.

Communicate & Connect



False-Positive Fecal Occult Blood

False-positive fecal occult blood results may occur if patients have ingested fish, meat that contains a high amount of heme (such as beef and lamb), or foods that contain peroxidase, including some fruits and vegetables. Fruits that may cause false-positive results include bananas, cantaloupe, pears, and plums. Vegetables that may cause false-positive results are broccoli, tomatoes (including tomato sauce), cauliflower, horseradish, and turnips. Patients should be instructed to avoid these foods for a few days prior to stool specimen collection. Aspirin and vitamin C must also be avoided because they may interfere with the guaiac test.

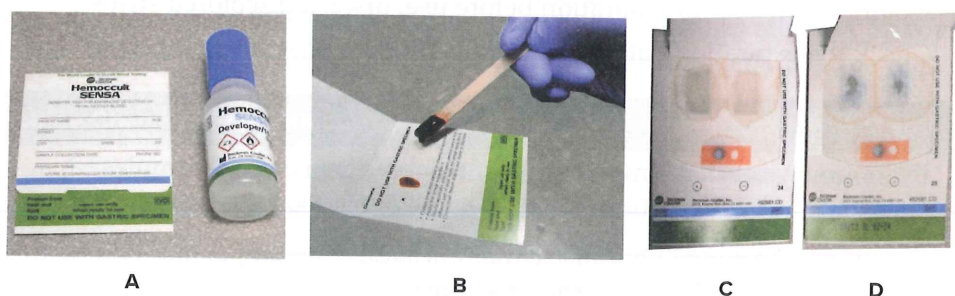


Figure 15-18 (A) Hemocult (Beckman Coulter, Inc.) card and hydrogen peroxide developer. (B) A small amount of stool is applied to the front of the card. (C) No blood detected. (D) Blood is present.

©Beckman Coulter

Checkpoint Questions 15.7

1. What substances may cause a false-positive result when testing for occult blood by the guaiac method?
2. What circumstances may cause a false-negative result in a waived test for fecal occult blood?

15.8 Point-of-Care Testing (POCT)

Point-of-care testing (POCT), or near-patient testing, is designed to reduce healthcare costs while enhancing patient care by making results available quickly. These tests involve collecting a specimen and immediately testing it on an instrument typically at the patient's side. The purpose of POCT is to reduce the turnaround time for test results. POCT instruments are typically portable, internally calibrated, easy-to-use, self-contained devices that can be operated with minimal training. The instruments are designed to make tests less dependent on the technical skill of the operator. Depending on the healthcare environment, these tests are usually performed by a phlebotomist, nurse, patient care technician, or medical assistant.

Examples of POCT blood tests include glucose, hemoglobin, sodium, potassium, chloride, bicarbonate, ionized calcium, cholesterol, blood ketones, blood gases, and coagulation studies, such as prothrombin time (PT). Other waived tests, mentioned earlier, may also be performed as POCT tests, including urine dipstick, urine pregnancy and ovulation tests, fecal occult blood, and screening for infections, such as Group A *Streptococcus*.

Home Monitoring of Glucose Levels

Patients who are monitoring their glucose at home should be instructed in the proper handling and maintenance of their glucose meter, as well as the correct method for glucose testing. They should also be informed of factors besides diet that affect their glucose level, such as physical and emotional stress. Patients should keep a detailed log of all the glucose testing they perform at home and provide this information to their primary care provider.



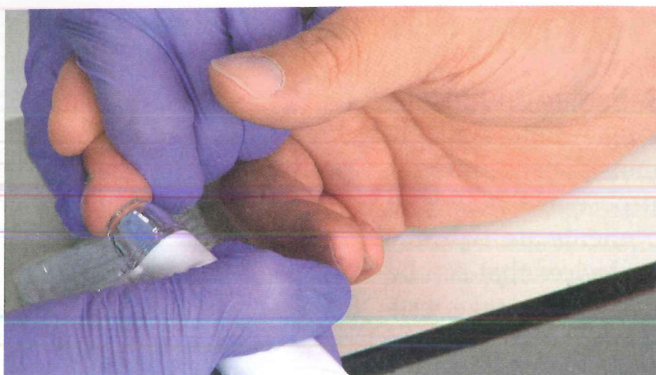
**Communicate
& Connect**

POCT tests typically require a small amount of blood from a dermal (capillary) puncture. However, each instrument is specific to the type of test, so the type and collection requirements of the specimen depend on the manufacturer's recommendations. All POCT instruments should be calibrated on a regular basis. Calibration and testing procedures are found in the manufacturer's directions. Regular calibration and instrument checking must be documented in a logbook at the facility where you are employed.

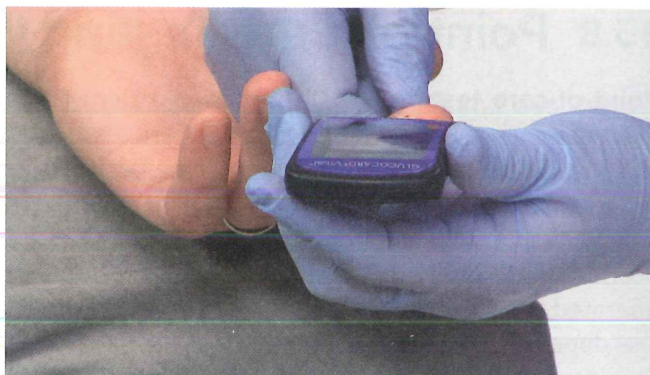
Glucose Testing

Glucose testing is used to screen for abnormal glucose levels and to monitor glucose levels in patients with diabetes mellitus (high blood glucose levels). Glucose testing is a critical part of diabetes management. Patients can even perform these tests at home. A POCT glucose determination allows frequent monitoring of a patient's blood at any time in any location. Changes in blood sugar can be handled immediately, and patients tend to be more compliant when they obtain immediate results. Testing provides the opportunity for better regulation of the patient's medication and condition.

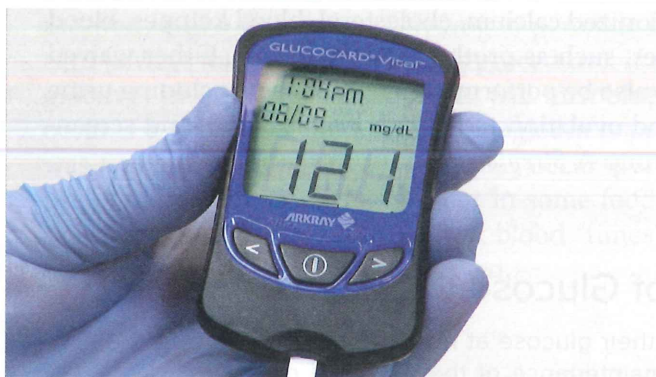
Several brands of glucose meters are available for POCT glucose. Methods vary by manufacturer. Phlebotomists and other meter operators should refer to the specific operator's manual for their meters for proper instrument maintenance, storage, and handling of reagent strips, test performance, and interpretation. Control substances should always be run and levels verified to be within acceptable limits prior to running any patient specimens.



A



B



C

Figure 15-19 For POCT glucose monitoring, (A) a dermal (capillary) puncture is performed, (B) a drop of blood is applied directly to the test strip while in the glucometer, and (C) after testing is complete, the results are read and documented in the appropriate records.

A–C: ©McGraw-Hill Education/Take One Digital Media, photographer

Glucose POCT Procedure

In general, most POCT procedures for glucose testing follow a procedure similar to the one shown in Figure 15-19 and outlined in Learn How 15-3.

Learn How 15-3

Glucose Point-of-Care Testing

1. Properly identify the patient.
2. Use PPE appropriate to the procedure and as required by your facility.
3. Assemble the dermal (capillary) puncture equipment.
4. Verify that controls have been run on the glucose instrument and are in range.
5. Prepare the glucose instrument for testing (insert test strip).
6. Perform a routine dermal (capillary) puncture.
7. Wipe away the first drop if required by the manufacturer of the machine you are using. The first drop may contain tissue fluid and affect the results, although newer equipment allows you to use the first drop.
8. Apply a drop of blood to the test strip (following the manufacturer's requirements). Testing should begin automatically.
9. Provide postpuncture patient care.
10. Properly dispose of biohazards.
11. After the test is complete, read and record the results. Confirm if the patient is fasting or ate within the last 2 hours. The results will vary based on the patient's eating status.

Glucose test results are affected by dietary intake. When performing these tests it is essential to know the patient's intake and the type of glucose test ordered, as discussed in the chapter *Special Phlebotomy Procedures*.

Use the competency checklist *Point-of-Care Glucose Testing* at the end of this chapter to review and practice the procedure.

Chemistry Panel

In addition to glucose, other analytes can be tested using POCT instrumentation. One such instrument is the Abbott i-STAT[®] (Figure 15-20), which is a hand-held analyzer that uses test cartridges with biosensors for specific substances. Some of the cartridges available for the i-STAT[®] measure levels of blood gasses, electrolytes, cardiac markers, hemoglobin, and coagulation tests. Tests can be performed on properly collected atrial, venous, or capillary specimens. Results can be printed or sent directly to a health information system via the docking station.

Hemoglobin

HemoCue[®] manufactures another POCT hemoglobin test instrument. A hand-held analyzer and microcuvettes make up the HemoCue[®] system (Figure 15-21). Whole blood from an EDTA sample or directly from a capillary puncture flows directly into the microcuvette, which is then inserted into the analyzer. Measurements are made at two different wavelengths and a result is displayed. Results can be sent directly to a health information system via wireless connection. If unexpected results are obtained, a second capillary puncture may be necessary and should be performed by a different person (phlebotomist or technical staff). Factors that can cause unreliable results include, but are not limited to, patient's capillary circulation, puncture technique, sampling technique, and instrument handling.



Figure 15-20 Abbott i-STAT[®] system: printer, iSTAT analyzer in docking station, and test cartridges.
Lillian Mundt



Figure 15-21 HemoCue[®] analyzer with microcuvette inserted.
Hemocue

1. What is the purpose of POCT?
2. Why do some equipment manufacturers suggest wiping away the first drop of blood after dermal (capillary) puncture before testing the blood glucose level by POCT methods?

 **Checkpoint
Questions 15.8**

Chapter Summary

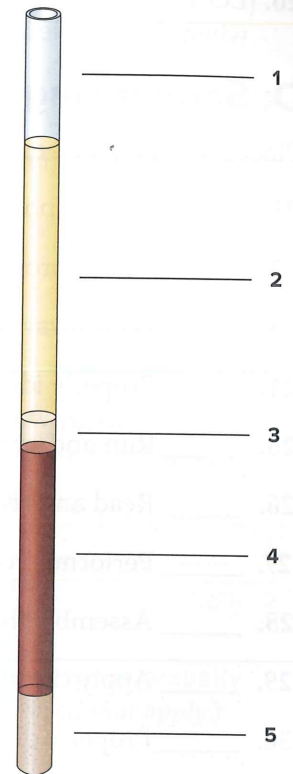
Learning Outcome	Key Concepts/Examples	Related NAACLS Competency
15.1 Differentiate among waived tests, moderate complexity tests, and high complexity tests.	<ul style="list-style-type: none"> The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) identified the following levels of complexity for medical laboratory tests: waived tests, moderate complexity tests, provider-performed microscopy procedures, and high complexity tests. A Certificate of Waiver is needed for facilities wishing to perform waived testing. 	N/A
15.2 Identify methods of performing an erythrocyte sedimentation rate.	The erythrocyte sedimentation rate (ESR) is the rate at which RBCs settle in whole blood. Several methods are used, including Wintrobe, Westergren, and modified Westergren. Factors that may affect ESR results include time from collection to testing, testing time, temperature, tilting, and vibrations.	4.3, 4.6, 5.1, 5.5, 7.1
15.3 Explain the procedure for performing a microhematocrit and the reasons why this test is performed.	A microhematocrit screens for anemia by measuring the packed cell volume of RBCs, or the percentage of RBCs in whole blood. Two capillary tubes are filled with blood from a dermal (capillary) puncture or with blood from a microcollection container or evacuated tube. The tubes are then centrifuged, and the percentage of RBCs is read on a microhematocrit-reading device.	4.6, 5.1, 5.5, 7.1
15.4 Describe the general procedure for performing a rapid diagnostic test on blood for infectious diseases.	RDTs that use blood are designed to detect antibodies made in response to infection. When a specimen is applied to a test cartridge containing the antigens for a specific organism, the antibodies in the specimen are bound to the test cartridge. A developer solution is added so that the reaction is visible as a band of color if positive and a band in the control area to indicate the test was performed correctly. Results are read according to the manufacturer's instructions.	5.1
15.5 Describe the general procedure for performing a rapid diagnostic test for respiratory infections.	RDTs for respiratory infections are designed to detect an antigen on the pathogenic organism. Test cartridges contain antibodies to this antigen. The antigens from a swab extraction react with the antibody particles in the cartridge, producing a visible line in the area if positive and a line in the control area to indicate the test was performed correctly. Results are read according to the manufacturer's instructions.	5.1
15.6 List the types of waived tests that are commonly performed on urine specimens.	Urine is routinely tested to determine whether a woman is pregnant, as well as to evaluate substances found in the urine. Urine tests can help determine wellness. The chemical screening portion of a urinalysis can be performed using waived testing methods such as the dipstick test.	4.3, 4.6, 7.1
15.7 Describe the waived procedure to test for fecal occult blood.	The waived tests for testing stool for occult blood involve the use of guaiac, a chemical that turns blue when blood is present. Several samples from the stool specimen are applied in a thin layer to the front of a card impregnated with guaiac. Hydrogen peroxide is added to the back of the card. If the guaiac paper turns blue, blood is present in the stool.	4.3, 5.1, 5.2, 5.5, 7.1, 7.3
15.8 Explain the purpose of point-of-care testing.	Point-of-care testing reduces the turnaround time for test results. In most cases, the specimen is tested immediately after collection with easy-to-use testing devices. Examples of POCT blood tests include glucose, hemoglobin, sodium, potassium, chloride, bicarbonate, ionized calcium, cholesterol, blood ketones, blood gases, and coagulation studies.	4.3, 4.6, 7.1, 7.3

Chapter Review

A: Labeling

Label the areas on the hematocrit test shown in the following image.

1. [LO 15.3] _____
2. [LO 15.3] _____
3. [LO 15.3] _____
4. [LO 15.3] _____
5. [LO 15.3] _____



B: Matching

Match each description with the level of laboratory testing. The levels may be used more than once. [LO 15.1]

- | | |
|---|---|
| ___ 6. grouped with moderate complexity tests | a. high complexity tests |
| ___ 7. easy to perform and interpret | b. moderate complexity tests |
| ___ 8. have a few procedural steps | c. provider-performed microscopy procedures |
| ___ 9. have numerous steps | d. waived tests |
| ___ 10. incorrect procedures cause no reasonable risk of harm | |
| ___ 11. include running automated instruments | |
| ___ 12. little manipulation of specimens or reagents | |
| ___ 13. may be used for at-home testing | |
| ___ 14. performed by healthcare providers on their own patients | |
| ___ 15. performed by personnel with specialized training | |
| ___ 16. require close attention to detail | |

C: Fill in the Blank

Write in the word(s) to complete the statement.

17. [LO 15.7] A strep test is used to screen for Group _____ *Streptococcus*.
18. [LO 15.6] A(n) _____ is a plastic strip containing pads that are impregnated with reagents.

19. [LO 15.2] Methods for performing erythrocyte sedimentation rates include _____, _____, and _____.
20. [LO 15.3] If occult blood is present in a stool specimen, the guaiac card will turn _____ when the sample is added and _____ is applied.

D: Sequencing

Place the steps for performing a POCT glucose test in the correct order (from 1 to 11). [LO 15.8]

21. _____ Provide postpuncture patient care.
22. _____ Don appropriate PPE.
23. _____ Wipe away the first drop of blood, if required.
24. _____ Properly identify the patient.
25. _____ Run and/or verify controls on the glucose instrument.
26. _____ Read and record the results.
27. _____ Perform a routine dermal (capillary) puncture.
28. _____ Assemble the equipment.
29. _____ Apply the blood to the test strip.
30. _____ Properly dispose of biohazards.
31. _____ Insert the test strip into the glucose instrument.

E: Case Studies/Critical Thinking

32. [LO 15.7] A specimen is tested for occult blood and found to be positive. A brief history on the patient revealed that he had recently eaten a meal that included steak with horseradish dressing. What is the most appropriate course of action?
33. [LO 15.6] When performing urine chemistry screening using reagent strips, you notice that the urobilinogen pad is already brown when you remove the strip from the container. What is your course of action? How might this strip have become discolored?

F: Exam Prep

Choose the best answer for each question.

34. [LO 15.2] An erythrocyte sedimentation rate is
- a. the distance RBCs settle in a calibrated tube after 1 hour.
 - b. the speed at which RBCs move through an automated analyzer.
 - c. how far red blood cells settle in the EDTA tube.
 - d. the percentage of red blood cells in a centrifuged capillary tube.
35. [LO 15.3] A microhematocrit is
- a. the percentage of red blood cells in a centrifuged capillary tube.
 - b. the amount of hemoglobin in the average red blood cell.
 - c. the number of red blood cells seen using a microscope.
 - d. none of these.

36. [LO 15.7] The guaiac card occult blood test is commonly performed on what type of specimen?
- Sputum
 - Stool
 - Throat swab
 - Urine
37. [LO 15.7] False-positive results may occur in a fecal occult blood test if patients have ingested (*Choose all that apply.*)
- alcohol.
 - bananas.
 - milk.
 - horseradish.
38. [LO 15.7] A microhematocrit test is used to screen for
- anemia.
 - diabetes mellitus.
 - occult blood.
 - strep infection.
39. [LO 15.6] Testing for human chorionic gonadotropin assesses the status of
- pregnancy in women.
 - male fertility.
 - Streptococcus* infection.
 - None of these.
40. [LO 15.6] Points of concern when using reagent strips for urine chemical testing include (*Choose all that apply.*)
- the time urine is in contact with reagent pads.
 - the removal of excess urine off the reagent pads.
 - correct comparison of the color changes of the reagent pads.
 - the time of day the specimen was collected.
41. [LO 15.8] What is POCT?
- Physician-ordered chemistry test
 - Patient-operated cholesterol test
 - Point-of-care testing
 - Personnel occupational care training
42. [LO 15.8] The blood glucose test is performed by
- applying blood to a strip inserted into a specially designed electronic meter.
 - using a urine reagent strip to test for glucose.
 - allowing blood to settle in a calibrated tube and measuring the distance.
 - applying blood to a guaiac card and adding hydrogen peroxide.
43. [LO 15.1] Levels of laboratory testing complexity were established by
- CAP.
 - CLIA.
 - CLSI.
 - COLA.
44. [LO 15.2] For which of the following does an ESR test screen?
- High blood pressure
 - Inflammation
 - Anemia
 - Jaundice
45. [LO 15.5] Which of the following cause respiratory infections? (*Choose all that apply.*)
- Groups A *Streptococcus*
 - Influenza A&B viruses
 - Respiratory syncytial virus
 - SARS-CoV-2 virus
46. [LO 15.4] Which of the following are sexually transmitted diseases? (*Choose all that apply.*)
- COVID
 - FLU
 - HIV
 - RSV
47. [LO 15.4] Which statements are true for rapid tests performed on blood?
- RDTs detect organism antigens present in blood.
 - RDTs detect antibodies present in blood.
 - Organism specific antibodies are on the test strip membrane.
 - Organism antigens are on the test strip membrane.
48. [LO 15.5] Which statements are true for rapid tests for respiratory infections?
- RDTs detect organism antigens present in the specimen.
 - RDTs detect antibodies present in the specimen.
 - Organism specific antibodies are on the test strip membrane.
 - Organism antigens are on the test strip membrane.

49. [LO 15.5] Which test, if negative, should be follow-up with a culture?

- a. COVID-19
- b. FLU A&B
- c. HIV 1&2
- d. Strep A

50. [LO 15.5] The SARS-CoV-2 virus causes

- a. COVID-19
- b. FLU A&B
- c. HIV 1&2
- d. RSV A&B



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NAME: _____ DATE: _____

COMPETENCY CHECKLIST: URINE CHEMICAL SCREENING

Procedure Steps	Practice			Performed		Master
	1	2	3	Yes	No	
Preprocedure						
1. Examines the requisition.						
2. Matches requisition identification with the specimen identification.						
3. Labels a report form correctly with the patient's identification or opens the correct patient's electronic laboratory test reporting form.						
4. Washes hands and dons appropriate PPE (lab coat, gloves, eye protection, or face shield).						
5. Assembles appropriate equipment (reagent strips, absorbent material, and biohazard waste container).						
Procedure						
6. Ensures that the specimen is at room temperature.						
7. Thoroughly mixes the specimen before removing the cap.						
8. Correctly removes a reagent strip from its bottle (does not contaminate other strips; replaces cap on the bottle) and ensures that it has not expired.						
9. Correctly dips the reagent strip into the urine (submerges all reagent pads).						
10. Immediately removes strip, dragging it across the top of the container and/or touching it gently on absorbent material to eliminate dripping.						
11. Begins timing immediately.						
12. Compares reagent strip pad colors to the chart on the bottle at the correct time.						
13. Selects the correct reaction reading for each test pad on the reagent strip.						
14. Correctly records results onto the result form or patient chart (or electronic record) including lot number and expiration date of the reagent strips.						
Postprocedure						
15. Properly disposes of reagent strip, specimen, and PPE.						

COMMENTS: _____

SIGNED

EVALUATOR: _____

STUDENT: _____

NAME: _____ DATE: _____

COMPETENCY CHECKLIST: POINT-OF-CARE GLUCOSE TESTING

Procedure Steps	Practice			Performed		
	1	2	3	Yes	No	Master
Preprocedure						
1. Performs quality control on the glucose meter.						
2. Records quality control and verifies that the meter is within control limits.						
3. Examines the requisition.						
4. Greets the patient; introduces self.						
5. Identifies the patient verbally using two identifiers, including comparing the identification band, if available, with the requisition.						
6. Explains the procedure to the patient.						
7. Verifies diet restrictions or instructions.						
8. Puts on gloves.						
9. Selects the correct equipment and supplies.						
10. Assembles the equipment and supplies properly.						
11. Conveniently places the equipment.						
12. Reassures the patient.						
13. Selects the appropriate finger.						
14. Warms the finger, if necessary.						
15. Selects the dermal (capillary) puncture site.						
16. Cleanses the puncture site.						
17. Allows the site to air dry.						
Procedure						
18. Applies the lancet across the fingerprints.						
19. Uses adequate pressure when activating the lancet.						
20. Wipes away the first drop of blood if required by the manufacturer of the machine being used.						
21. Follows the manufacturer's procedure for performing glucose analysis.						
22. Places gauze over the puncture site.						
23. Records the glucose level correctly.						
Postprocedure						
24. Thanks the patient.						
25. Disposes of used supplies appropriately.						
26. Removes gloves and washes hands.						
27. Documents the results in the computer system (if required).						

COMMENTS: _____

SIGNED

EVALUATOR: _____

STUDENT: _____

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