

Point of Care Collection and Testing

A. Point-of-Care Collection and Testing

1. Laboratory testing brought to the patient's location is most commonly known as ***Point of Care Testing (POCT)***.
 - a. Other names include:
 - 1) Decentralized laboratory testing
 - 2) On-site
 - 3) Alternate-site testing
 - 4) Near-patient
 - 5) Patient-focused testing
 - 6) Bedside testing
 - b. POCT has several advantages:
 - 1) Convenience- can be done in a doctor's office, at the bedside, at home.
 - 2) Short turnaround time (TAT), immediate results for quicker treatment decisions.
 - 3) Many POCT are performed on whole blood collected by capillary puncture, other POCT use saliva, throat swabs or urine.
 - c. Technology has led to a variety of POCT methods.
 - 1) Advances have led to small, portable instruments, some of which are hand-held.
 - 2) Kit tests, which have everything needed for testing in a pre-packaged format.
 - d. Results of POCT must correlate with the same test performed in the lab.
2. ***Waived test***, as defined by CLIA, meet the following criteria:
 - a. Test is simple, easy to perform.
 - b. Low risk of inaccurate, incorrect results.
 - c. Risk to the patient is low.
3. While many POCT have waived status, some do not.

Example: Instruments that measure blood gasses for use in the ICU measure several analytes, are more complex, and inaccurate results can have serious

consequences for the patient. These instruments may or may not have waived status.

4. Many waived tests are POCT, but some are not.

Example: Erythrocyte Sedimentation Rate (ESR) is a waived test that requires a vibration free location for testing and takes 30 - 60 minutes to perform.

5. Training requirements for Point-of-Care and Waived test procedures.
 - a. Personnel performing tests must meet CLIA requirements, as well as state and local requirements.
 - b. Training must be documented for the specific equipment being used.
 - c. Training on the correct specimen collection procedure must be documented.
 - d. Careful reading of the procedure, user manual and package inserts to understand the following:
 - 1) Substance being tested and principal of the procedure.
 - 2) Manufacturer's instructions for proper performance of the test and operation of equipment.
 - 3) Proper storage and use of controls, standards, and supplies.
 - e. Quality Control procedures – procedures that must be followed and performed to ensure that test results are correct and accurate.
 - 1) Internal Quality control – found in many instruments to check electronic operation.
 - 2) External Quality Control – material of known concentration that resembles patient testing, to verify that testing and materials used are functioning correctly.
 - i) The frequency of external quality control must meet or exceed the manufacturer's instructions.
 - ii) Daily quality control is required on most POC tests using instrumentation. Examples: Glucose, Hemoglobin A1c, Hemoglobin
 - iii) Periodic quality control is performed on kit type tests when a new lot of cassettes are opened. These tests have built-in controls to indicate if the cassette is working properly. Examples: Pregnancy test, Immunochemical Fecal Occult Blood

- f. Routine maintenance, internal cleaning procedures and battery replacement.
 - g. Infection Control and Safety
 - 1) CDC's Standard Precautions must be followed for specimen collection.
 - 2) POCT must adhere to OSHA's Bloodborne Pathogen Standard and Needle Safety & Prevention Act.
 - 3) Handheld instruments used in the presence of the patient must be properly disinfected prior to being used on the next patient. Instrument disinfection should follow manufacturers recommendation and facility policy.
 - 4) Disinfection can be accomplished by wiping down the outside of the equipment using one of the following:
 - i) A 10% bleach solution, prepared fresh daily.
 - ii) An individually wrapped EPA-registered bleach wipe that meets OSHA and CDC regulations.
 - h. Troubleshooting resources - user's manual, online websites.
6. Proper documentation of patient testing is vital and includes the following:
- 1) Date and time of testing.
 - 2) Lot number and expiration date of reagents, controls and disposable supplies, such as test strips or cuvettes.
 - 3) Proper recording of both internal and external controls and patient results.
 - 4) Controls must have the mean and standard deviation calculated and plotted.
 - 5) Name or initials of individuals performing test and recording results.
 - 6) Documentation of cleaning, routine maintenance and battery replacement as well as malfunctions and repairs.
- 7 . Potential sources of error in Point of Care Testing
- a. Patient issues
 - 1) Correct patient is identified correctly following facility protocols.
 - 2) Patient has followed the proper diet for the test (Glucose, FOB test).

b. Specimen collection and handling issues

- 1) Blood is contaminated/diluted with alcohol that was not allowed to dry.
- 2) Blood is hemolyzed by alcohol that was not allowed to dry.
- 3) Wrong volume of specimen is collected.

c) Timing issues

- 1) Collection of the specimen is not at the optimum time for best test results.
- 2) Timing of the analytic procedure is incorrect.

d) Issues with reagents, controls or supplies

- 1) Reagents, controls or supplies (test strips, cuvettes) are out of date.
- 2) Reagents, controls or supplies were not stored at the proper temperature or under the proper conditions and have deteriorated.
- 3) Controls are not used properly.

e) Instrument issues

- 1) Instruments are not clean, routine maintenance is not performed.
- 2) Blotting or wiping technique is not performed properly.
- 3) Battery is weak or dies during testing.

f) Documentation and reporting issues

- 1) Clerical error of test results, time and date of testing.
- 2) Clerical error of control results.
- 3) Results not sent in a timely fashion to appropriate healthcare providers.

B. Glucose Monitoring

1. Most common point-of-care test.
2. Used to determine blood glucose levels to *monitor* patients with diabetes mellitus.
3. Glucose meters are not intended for the diagnosis of diabetes as they tend to have a different reference range because they test whole blood from a capillary sample.
4. Two categories of glucose meters:
 - a. Meters for diabetics to use at home to monitor their glucose level and adjust medications as necessary. These include:

- 1) Freestyle Lite
- 2) One Touch Ultra
- 3) Accu-Chek Compact Plus

b. Meters used in hospitals and other healthcare settings. These instruments utilize more extensive Quality Control to ensure accuracy and can connect to electronic medical records to eliminate clerical errors. These include:

- 1) HemoCue β -Glucose Analyzer
- 2) Nova StatStrip
- 3) Starstrip Xpress Glucose Hospital Meter System

C. Hematocrits, Hemoglobin, and Other Hematology Parameters

1. The hematocrit represents the volume of a whole blood sample which are Red Blood Cells and is expressed as a percentage.
 - a. Hematocrits are used to aid in the diagnosis of anemia.
 - b. Can be performed using the StatSpin CritSpin microhematocrit centrifuge or a traditional microhematocrit centrifuge.
2. Hemoglobin is the substance in the red blood cell which transports oxygen to the tissue and is used to aid in the diagnosis of anemia.
 - a. The American Medical Association (AMA) has determined that the hemoglobin is more accurate for anemia diagnosis than the hematocrit.
 - b. A variety of instruments are available that use micro-cuvettes.
 - 1) The HemoCue Hb 201+
 - 2) The HemoPoint H2 System
3. Automated instrumentation is available to perform additional hematology test, such as the platelet count, hemoglobin, hematocrit, WBC count and RBC count in a POCT setting.

D. Blood Coagulation Monitoring

1. Used for controlling bleeding or clotting disorders in patients as well as monitoring anticoagulation therapy, such as heparin or warfarin (Coumadin).
2. POC coagulation test include:
 - a. Prothrombin Time (PT)
 - b. Activated partial thromboplastin time (aPTT or PTT)

- c. Activated clotting time (ACT)
 - d. Platelet function
 - e. International Normalized Ratio (INR) – a mathematical formula which standardizes the differences between various manufacturer’s PT reagents.
 - 2. Examples of POC coagulation instrumentation include:
 - a. CoaguChek XS Plus System
 - b. ITC ProTime Microcoagulation System
 - c. Actalyke XL Activated Clotting Time Test (ACT) System
 - d. Alere INRatio2 Meter
 - 3. Proper training in use, preventive maintenance and QC is critical.
- E. Other Chemistry POCT
- 1. Nova Stat Profile Prime Critical Care System – used in critical care units for the following:
 - a. Blood Gas (pH, pO₂, pCO₂)
 - b. Electrolytes (Sodium, Potassium, Chloride, CO₂, Ionized Calcium)
 - 2. Roche TROPT - measures troponin T to detect heart damage.
 - 3. Chemcard Cholesterol Test and the Alere Cholestech LDX System – for measurement of cholesterol and other lipids.
 - 4. BiliCheck – for measuring bilirubin in newborns.
 - 5. StatSensor Point-of Care Creatinine and eGFR Analyzer – for whole blood creatinine testing.
 - 6. DCA Vantage Analyzer – measures glycosylated hemoglobin (HbA1c) to monitor diabetes treatment.
- F. Kit Test
- 1. These types of POCT do not usually require instrumentation. Everything that is needed for performing the test is included in the package (the “kit”).
 - 2. As with other POCT, it is important to have proper training and follow the manufacturer's instructions carefully for both the collection of the sample and the performance of the testing for accurate results.
 - 3. Kit test are available for a wide variety of analytes, including the following:
 - a. Pregnancy test

- b. Strep screening
- c. Flu testing
- d. Immunochemical Fecal Occult Blood
- e. HIV testing

References

- McCall and Tankersley(2016) *Phlebotomy Essentials*, 6th edition. Philadelphia, PA: Wolters Kluwer
- Garza and Becan-McBride(2019) *Phlebotomy Handbook*, 10th edition. New York, New York: Pearson