



Ambulatory Clinic Policy and Procedure

Title: POINT-OF-CARE TESTING	Policy Number: EP 3.19
Regulation Reference: CMS, Joint Commission	Effective Date: 11/2023

Policy Statement:

It is the policy of the Texas Tech Physicians of El Paso (TTP-EP) to establish guidelines for Point-of-Care Testing (POC) to ensure that manufacturer's guidelines, quality control, and competency testing procedures are followed to ensure quality patient care.

Scope and Distribution:

This policy applies and will be distributed to all Texas Tech Physicians of El Paso ambulatory clinics.

Procedure:

1. All clinical departments performing POC waived testing must have a valid Clinical Laboratory Improvement Amendment (CLIA) certificate. The provider listed on the CLIA certificate will be the person responsible for oversight of all POC tests performed in the department.
2. Clinics are to maintain a current list of all POC testing performed in the clinic. These lists are to be reviewed on a yearly basis or updated when POC tests are added or removed.
3. Clinics are to maintain a current list of individuals authorized to supervise waived testing activities using the Designation of Waived Testing Supervision (attachment C and D).
4. Personnel who are involved in testing patient samples or performing quality controls must be evaluated for color blindness.
 - a. Nurse Managers should contact the Office of Occupational Health to schedule a color blindness evaluation during the employee's orientation to their duties prior to the employee performing any POC tests (attachment A).
 - b. Results of testing will be kept in the Occupational Health File for the employee.
 - c. If a staff member is found to have some degree of color-blindness they should not perform tests with results or quality controls that require color differentiation.
 - d. These employees will be referred for follow up as appropriate.
5. All personnel performing POC testing must receive training and competency evaluation on performing tests on the samples and quality controls.
 - a. New employees expected to perform POC tests must undergo training on each test performed in the clinic along with a visual competency evaluation prior to performing any POC testing.
 - b. Existing employees must undergo yearly training on each test performed in the clinic along with a visual competency evaluation.
 - c. Documentation of staff POC training and competency evaluation must be sent to Human Resources for inclusion in the employee's file.

Training will include:

- a. Skills required for proper specimen collection
- b. Patient preparation skills



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- c. Labeling of specimen
- d. Proper handling of reagents
- e. Skills required for performing each test method and for proper use
- f. A working knowledge of reagent stability and storage
- g. Skills required to implement the quality control procedures
- h. An awareness of the factors that influence test results
- i. Skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results
- j. Completion of written test with a passing grade of 80%

Visual Competency evaluation will determine that:

- a. The individual can follow the procedure for specimen handling and processing, test analysis reporting and maintaining records of patient results.
 - b. The individual can adhere to procedural guidelines for quality control, calibration, and maintenance.
 - c. The individual can follow the established corrective action policies and procedures whenever test systems are not within the established acceptable levels of performance.
 - d. The individual is capable of identifying problems that may adversely affect test performance or reporting of test results and they can correct the problems or immediately notify the Nurse Manager.
 - e. The individual can document all corrective actions taken when test systems deviate from established performance specifications.
6. Quality controls will be performed on all POC tests per each test's manufacturer's recommendations.
- a. Documentation of quality controls and the outcomes are to be documented on the Quality Control Sheet (Attachment B) at the time the controls are performed. A separate Control Sheet will be kept for each type of test.
 - b. The Nurse Manager will review Control Sheets on a monthly basis to ensure accuracy and to evaluate any discrepancies with quality control performance.
 - c. Any discrepancies with quality control must be corrected prior to implementation for patient use.
 - d. If the manufacturer does not provide specific guidelines on quality controls then the following shall be used as a guide:
 - i. Fecal Occult Blood – Quality control will be accomplished by utilizing the “Performance Control Area” on the test card before each patient testing.
 - ii. Whole Blood Glucose – Quality controls must be performed before the first patient test each day the meter is used.
 - iii. Urinalysis – Two levels of quality controls will be performed with every new lot number if testing is performed manually, every 24 hours if patient testing is automated.
 - iv. Urine Pregnancy – Qualitative.
 - v. Rapid Strep Group A/Rapid Flu/Rapid RSV – Quality control must be performed for each lot number.
 - vi. Glucometer glucose checks – Quality controls must be performed before the first patient each day the meter is used.
 - vii. CoaguChek PT-INR – No external controls are necessary. The meter automatically runs its own quality control test as part of every blood test. This control must also be documented on the Quality Control Sheet along with all other POC tests.



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