


Responsibilities of Testing Sites and the Clinical Laboratory for Point of Care Testing (POCT)

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APPLICABLE LABORATORY(S):

- North Carolina Baptist Hospital (NCBH)
- Lexington Medical Center (LMC)
- Davie Medical Center (DMC)
- Wilkes Medical Center (WMC)
- High Point Medical Center (HPMC)
- Westchester
- Clemmons

PURPOSE

It is the policy of Atrium Health Wake Forest Baptist (AHWFB) to appropriately guide and provide compliance related support to sites that perform Point of Care Testing (POCT). Sites that perform blood or body fluid testing are responsible for disclosing such testing and are responsible for ensuring appropriate CLIA certificate coverage and compliance with applicable regulatory authorities.

Sites considering POCT implementation or method/procedure changes must submit an application to be reviewed by Point of Care Testing Compliance and the AHWFB Point of Care Testing Committee (POCTC). The application must be submitted prior to purchasing new equipment or initiating testing. The POCT application form and information are available on the POCT website on the Intranet. (Departments—Point of Care Testing—Applications for New Equipment and Tests).

As federal regulations state, failure to comply with CLIA regulations can lead to suspension, revocation, or limitation of certification and denial of Medicare/Medicaid payments to AHWFB. If the Point of Care Committee becomes aware of lapses in compliance with CLIA regulations at a site, the committee has the right to recommend discontinuation of testing at that site until remediation is satisfactorily completed.

SCOPE

All AHWFB staff members who are educated and qualified to perform waived and/or non-waived POCT by their job descriptions are responsible for following this policy.

Responsible Department/Party/Parties:

- i. Policy Owner: Manager Point of Care Testing Compliance
- ii. Procedure: The Laboratory Director listed on the address-specific CLIA certificate (and/or their qualified designee) will be responsible for the oversight of any areas performing point of care testing at that defined location. For non-waived point of care testing, education and competency assessment of the staff members performing

- testing will be the responsibility of the site-specific Technical Consultant and/or their qualified designee. For Waived/Provider Performed Microscopy Procedures (PPMP), education and competency assessment will be the responsibility of Nursing Administration (Clinical Nurse educator, RN preceptor, clinic coordinator or nurse manager) and/or the laboratory director for PPMP.
- iii. Supervision: The Laboratory Director, as indicated on the CLIA certificate for the clinic/area performing the test, Clinical Compliance Director, Point of Care Testing Compliance and WFBMC Department of Pathology.
 - iv. Implementation: The Laboratory Director as indicated on the CLIA certificate for the clinic/area performing testing and/or their designee.

DEFINITIONS

- A. **Policy:** A statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities. A policy may help to ensure compliance with applicable laws and regulations, promote one or more missions, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors, and others are expected to operate.
- B. **WFBH Lab System:** Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
- C. **Point of Care Testing (POCT):** Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.
- D. **Point of Care Testing Committee (POCTC):** Multi-disciplinary committee that reviews all applications for Point of Care Testing.
- E. **Waived Tests:** Tests of low complexity as designated by the FDA; tests that are simple and have low risk for erroneous results.
- F. **Non-Waived Tests:** Tests of moderate or high complexity as designated by the FDA.
- G. **Clinical Laboratory Improvement Amendments (CLIA):** United States federal regulatory standards that apply to all laboratory testing performed on humans.
- H. **College of American Pathologists (CAP):** Accrediting agency for the AHWFB Clinical Laboratory. Point of Care sites, included on the CLIA certificate of the Clinical Laboratory, are accountable to standards set forth by CAP.
- I. **Site Technical Consultant:** An individual holding a 4 year Bachelor's degree in a chemical, physical, biological science or medical technology from an accredited institution and has at least 2 years of laboratory training or experience, or both, in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
 - Note: Per information from the CLIA regional office, a 4 year Bachelor's degree in nursing is considered a biological science degree. Therefore, the 4 year Bachelor's degree nurse can function as a technical consultant, as long as the individual also has 2 years of training or experience in the specialty area of testing.
- J. **Approved Point of Care Tests Performed at Atrium Health Wake Forest Baptist (AHWFB):** Refer to Rules and Tools for Point of Care Testing Manual or POCT website on the intranet - <http://intranet.wakehealth.edu/Departments/Pathology/POCT/>.

POLICY GUIDELINES

1. The purpose of this policy is to establish an understanding of responsibilities between the Department of Pathology Clinical Laboratory and clinical area testing sites performing waived, Provider Performed Microscopy (PPM), and non-waived point of care lab tests by non-lab personnel. In addition, the purpose is to establish and maintain harmonization of POCT practice, i.e. reagents/equipment/kits, where possible, across the breadth of the organization, i.e. across multiple campuses and clinic sites.
 - A. The Clinical Laboratory is responsible for overseeing certain non-waived laboratory testing covered by the Clinical Laboratory CLIA certificate, CLIA ID 34D0664386. Contact the Point of Care Testing Compliance office for a current list of covered sites.
 - B. To facilitate compliance with regulatory agencies and the Federal Government, the POCT Compliance department can provide limited consultative services to user sites setting up waived, Provider Performed Microscopy (PPM), and moderate complexity testing.
 - C. The POCTC maintains limited oversight of waived, PPM, and moderate complexity testing. Limited oversight is defined as responsibility to review and approve applications and to assist with initial set-up for waived/PPM testing, as well as the tests/methods chosen.
 - D. Specific user-site responsibilities are outlined in the ***Point of Care Waived and Non-Waived Testing*** policy and related test-specific AHWFB procedures.
2. **Request to Implement Point of Care Testing -**

A POCT application form shall be completed and submitted to the Point of Care Testing Compliance office for review by the POCT Committee, as necessary – form attached to ***Point of Care Waived and Non-Waived Testing*** policy.
3. **Non-Waived Testing Responsibilities -**
 - a) Testing Sites Covered by the Clinical Laboratory CLIA Certificate shall adhere to federal CLIA regulations and the College of American Pathologists (CAP) standards.
 - b) Testing sites holding a separate CLIA certificate shall adhere to federal CLIA regulations and any other accrediting agency standards by which the testing is covered.
 - c) The POCT Compliance Office shall assist POCT sites, as needed, in complying with the requirements of CLIA and accrediting agencies.
 - d) POCT sites will be accountable for maintaining documentation of compliance with all regulating agencies.
4. **Clinical Laboratory POCT Responsibilities for Non-Waived Point of Care Testing covered by the Clinical Laboratory CLIA certificate -**

The AHWFB Point of Care Testing Compliance team will provide the following support:

 - A. Procedure:** Test procedures will be prepared to comply with current regulatory requirements, including specimen collection, specimen preparation, quality control, result reporting, and remedial action requirements. Procedures will be reviewed biennially and revised as necessary by the POCT Compliance Office or designee. All procedures will be approved by the CLIA Laboratory Medical Director before becoming Effective.
 - B. Training/Competency:** Training and competency assessment of testing site technical consultant will be provided. Testing personnel competency will be provided on an as-needed/temporary basis where there is no immediately qualifying site technical consultant. Training and competency assessment format will be provided to the site technical consultants.
 - C. Reagents:** Reagent records will be reviewed for accuracy and compliance.

- D. Equipment:** New and replacement equipment will be evaluated for accuracy, precision, linearity, interferences, etc., according to the applicable regulatory standards. The Clinical Laboratory will determine schedules for performance of quality control and maintenance. Laboratory staff will be available for instrument troubleshooting, if necessary.
- E. Instrument Maintenance:** Instrument maintenance records will be reviewed for compliance and accuracy.
- F. Testing Records:** Records will be reviewed by Point of Care Testing Compliance and testing site designee to ensure correct documentation of patient test and Quality Control (QC) results. To ensure compliance, the quality control data will be reviewed and assessed at least monthly by the CLIA laboratory director or qualified designee.
- G. Continuous Quality Improvement/Assurance:** Whenever possible, internal Quality Improvement/assurance (QI/QA) monitors will be developed, as appropriate, and may include turn-around-time measurements, periodic reassessment of costs, or practice assessment evaluations.
- H. Proficiency Testing:** As appropriate per CLIA regulations, a proficiency testing program will be chosen by the Clinical Laboratory. Proficiency testing results and records will be reviewed by the CLIA Laboratory Director to ensure good performance. As needed, remedial action will be determined by the CLIA Laboratory Director and communicated to the testing site manager and site technical consultant.

5. Testing Site Responsibilities for Non-Waived POCT –

Each testing site is accountable for the following, where applicable:

- A.** Testing sites must meet the requirements of CLIA and applicable accrediting agencies, such as The Joint Commission and the College of American Pathologists (CAP), and are responsible for following applicable Clinical Laboratory policies and procedures in relation to the point of care test and applicable quality assurance policies and procedures. These requirements are subject to modification when required to accommodate changes in standards from regulatory agencies.
- B. Documentation of Education:** Each testing staff member must have on file in the testing department a copy of diploma or completed transcript. Bare minimum education requirement for non-waived POCT personnel is a high school diploma.
- C. Site Technical Consultant:** Each testing site must designate an individual as the Site Technical Consultant. This individual is responsible for operational oversight and compliance for all POCT performed in their area. Refer to Site Technical Consultant definition for education/experience requirements.
- D. Procedure:** The test procedure manual must be available to staff who perform testing. All testing personnel must read the procedure manual at initial training and whenever changes are made to the manual/procedure(s). Review should be documented.
- E. Training/Competency:**
 - i. The testing site is responsible for ensuring that all testing personnel are trained and assessed to be competent to perform the testing.
 - ii. Competency testing must be performed to meet CLIA competency requirements for non-waived testing.
 - iii. During the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually.
 - iv. Competency assessment, which includes six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.

- v. The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing:
 - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
 - Monitoring the recording and reporting of test results;
 - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
 - Direct observations of performance of instrument maintenance and function checks;
 - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
 - Assessment of problem solving skills.
 - vi. Written competency must be passed with an eighty percent or higher grade.
 - vii. Observation competency must be passed with a level 3, "Competent and can perform independently".
 - viii. If an employee fails to achieve these passing requirements, then re-education and reassessment must be completed, prior to performing additional patient testing.
 - ix. Training and competency assessments must be documented and maintained by the testing department.
- F. Approved User List:** The test site manager or designee is responsible for maintaining a current list of approved testing personnel and for ensuring that testing personnel are trained and competent, per applicable regulatory standards.
- G. Reagent Records:** All reagent and supply records must be maintained. This includes recording the open date on the reagents and control materials and ensuring only reagents with current expiration dates are in use. An accurate audit trail should be maintained to allow tracking to specific patient results. For example, a Quality Control log noting the reagent lot numbers, date quality control checks performed, and expiration dates can be maintained.
- H. Instrument Maintenance:** Records must be maintained, including documentation of scheduled and unscheduled maintenance. An accurate audit trail should be maintained to allow tracking to specific patient results.
- I. Instrument and Reagent Back-Up:** Each testing site is responsible for maintaining an instrument down-time action plan in case of analyzer or reagent malfunction. The Clinical Laboratory POCT department is not responsible for maintaining loaner or reagent inventory for user sites. Appropriate back-up action plans should be in effect prior to the need.
- J. Testing Records:** Records must be maintained, indicating when and who performed patient testing and quality control testing. Each user site is responsible for performing required quality control checks on analyzers and reagents.
- K. Result Reporting:** Documentation is the responsibility of each testing site. This must include the person performing the test, date and time testing performed, and the test result with units of measure and applicable reference (normal) range. Patient test results should be documented in the patient's electronic medical record. A clear audit trail should be established for testing personnel, analyzer, and reagents used.

- L. Continuous Quality Improvement/Assurance:** As appropriate, proficiency testing should be performed by the testing site and performed by testing site personnel in an identical manner to patient samples. Testing sites will work with the POCT Compliance Office to quickly resolve any proficiency testing problems and any other identified quality assurance (QA) issues.
- M. New Tests and Equipment:** Prior to purchasing new equipment or implementing new test procedures for non-waived POCT at AHWFB, the user site must receive approval through processes established by the Clinical Laboratory. For example, the process may involve an application from the user site that includes, but is not limited to, descriptions of the equipment, tests to be performed, patient population to be tested, estimated volume and frequency of use, operator training requirements, data management, impact of Length of Stay (LOS) and outcome, safety data, quality control requirements, cost of equipment and reagents, current tests that will be replaced, and regulatory issues.
- N. Accreditation:** The POCT program will participate satisfactorily in accreditation inspections by appropriate agencies. Any site which is non-compliant with AHWFB POCT and Clinical Laboratory policies and regulatory agency requirements jeopardizes coverage by the Clinical Laboratory CLIA certificate.
- O. Documentation:** For all sites at AHWFB Medical Center, all records for non-waived POCT will be forwarded to the Clinical Laboratory POCT Office for storage. Each site should also maintain copies of all records related to POCT performed at the site, including training, competency, QC and maintenance logs as applicable.

6. Clinical Laboratory POCT Responsibilities for Waived and Provider Performed Microscopy (PPM) Testing -

- The AHWFB Clinical Laboratory POCT department will work cooperatively with user sites in a limited consultative role to facilitate initial set-up and continued testing site compliance with CLIA and other accreditation agencies and in accordance with the ***Point of Care Waived and Non-Waived Testing*** policy. Compliance considerations include, but are not limited to:
 - i. Procedures
 - ii. Training and Competency
 - iii. Reagent (selection, storage, and documentation)
 - iv. Equipment
 - v. Instrument Maintenance
 - vi. Continuous Quality Improvement
 - vii. Test Records (QC and Patient Documentation)
 - viii. Accreditation
 - ix. Proficiency Testing

7. User Site Responsibilities for Waived and PPM Testing –

- A. User site responsibilities are defined in the ***Point of Care Waived and Non-Waived Testing*** policy and AHWFB test-specific procedures for waived and PPM testing.
- B. All applicable regulatory and accrediting agency standards should be followed.
- C. Sites should notify the POCT Coaches team at POC_Audit_DL@wakehealth.edu when there is a change in the CLIA Lab Director or clinic/test site location. A current copy of the CLIA certificate should be provided.

8. Clinical Laboratory Contact Information

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LITERATURE REFERENCES:

Centers for Medicare and Medicaid Services, Department of Health and Human Services, Code of Federal Regulations (42 CFR 493), Laboratory Services.

College of American Pathologists (CAP) Lab Accreditation Program Lab General, All Common, and Point of Care Testing checklists, CAP, 325 Waukegan Rd, Northfield, Illinois 60093-2750, Revised 6/2022.

Comprehensive Accreditation Manual for Hospitals, 2022 by the Joint Commission on Accreditation of Healthcare Organizations (Waived Testing Chapter, Standards: WT.01.01.01,WT.02.01.01,WT.03.01.01,WT.04.01.01,WT.05.01.01).

RELATED PROCEDURES/POLICIES IN NAVEX AND/OR ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

Point of Care Waived and Non-Waived Testing
Non-Waived POCT Quality Management Policy and Quality Control/Quality Assurance Procedures
Resulting Point of Care Tests in WakeOne
Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.