Wake Forest Baptist Medical Center	**Understanding of Responsibilities between Testing Sites and the Clinical Laboratory for Point of Care Testing (POCT)** Formerly: PPB-WFBMC-NCBH-95	**Type:**	**Tier * 3**
		Original Effective Date:	**6/17/96**
		Current (Revised) Date:	**08/2020**
		Contact:	**Point of Care Testing Compliance**
CLIA Laboratory Medical Director Signature: **Signature on File**		**Date Approved:**	
Name and Title: **Gregory Pomper, MD, Medical Director, Clinical Laboratories**			

1) General Policy Statement:

It is the policy of Wake Forest Baptist Medical Center (WFBMC) 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 WFBMC 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 WFBMC 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 WFBMC. 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.

a) Scope: All staff members who are educated and qualified to perform point of care testing indicated by their job descriptions are responsible for following this policy.

b) 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 tests and/or their designee.

2) Definitions: For purposes of this Policy, the following terms and definitions apply:

a) WFBMC: Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.

b) Policy: As defined in the Policy on Creating and Amending 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 of WFBMC. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.

c) Point of Care Testing Committee (POCTC): Multi-disciplinary committee that reviews all applications for Point of Care Testing.

d) Point of care testing (POCT): Medical testing at or near the site of patient care, does not require permanent dedicated space and is performed outside the physical facilities of the clinical laboratory. Regardless of the location, any blood or body fluid testing/evaluation that is used for treatment or care of a patient must maintain and be covered by a valid CLIA certificate.

e) Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all laboratory testing performed on humans.

f) College of American Pathologists (CAP): Accrediting agency for the WFBH Clinical Laboratory. Point of Care sites, included on the CLIA certificate of the Clinical Laboratory, are accountable to standards set forth by CAP.

g) 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.

3) Policy Guidelines

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 Clinical Laboratory can provide limited consultative services to user sites setting up waived and Provider Performed Microscopy (PPM) testing.

c) The POCTC maintains limited oversight of waived and PPM 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 Testing policy and related test-specific WFBMC procedures.

4) 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.

5) 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 WFBMC Clinical Laboratory 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.

6) Clinical Laboratory Responsibilities for Non-Waived Point of Care Testing covered by the Clinical Laboratory CLIA certificate

The WFBMC 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 preservation, quality control, result reporting, and remedial action requirements. Procedures will be reviewed biennially and revised as necessary by the Clinical Laboratory Medical Director or their qualified designee.

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: Whenever possible, internal Quality Improvement (QI) 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.

7) Testing Site Responsibilities for Non-Waived POCT

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.

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

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 present in the testing area. 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 re-assessment 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 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 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:** 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 Clinical Laboratory to quickly resolve any proficiency testing problems and any other identified quality improvement (QI) issues.

m) **New Tests and Equipment:** Prior to purchasing new equipment or implementing new test procedures for non-waived POCT at WFBMC, 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 WFBMC POCT and Clinical Laboratory POCT policies and regulatory agency requirements jeopardizes coverage by the Clinical Laboratory CLIA certificate.

o) **Documentation:** All records for non-waived POCT will be forwarded to the Clinical Laboratory for storage. Each site should also maintain copies of all records related to POCT performed at the site, including training, competency, and QC logs.

8) Clinical Laboratory Responsibilities for Waived and Provider Performed Microscopy (PPM) Testing

a) The WFBMC Clinical Laboratory 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 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

9) 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 WFBMC test-specific procedures for waived and PPM testing.
b) Regulatory and accrediting agency standards should be followed.
c) Provider-based clinics will also be subject to The Joint Commission hospital waived testing standards.
d) Sites should notify the POCT Compliance office at LabPOC_Testing_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.

10) Clinical Laboratory Contact Information

a) Medical Director – Clinical Laboratory
Greg Pomper, MD
336-716-7442
gpomper@wakehealth.edu

b) Administrative Director – Clinical Laboratory
Lauren Elmore
336-716-1398
lelmore@wakehealth.edu

c) Manager Point of Care Testing Compliance
Liz Gregory, BSMT (ASCP)
336-713-0377
liz.gregory@wakehealth.edu

d) Point of Care Testing Compliance
LabPOC_Testing_DL@wakehealth.edu

11) Review/Revision/Implementation

a) Review Cycle: Each 2 years
i. All new policies/procedures/guidelines and those that have major revisions must be reviewed/signed by the CLIA Laboratory Medical Director.
ii. Review/sign-off can be completed by the designated section Medical Director or section manager in the following circumstances:
- Biennial review
- Minor document revisions

b) Office of Record: Point of Care Testing Compliance

12) Related Policies

Added as links to procedure

13) Governing Law or Regulations

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

b) 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 6/2020

c) Comprehensive Accreditation Manual for Hospitals, 2020 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)

14) Attachments

None

15) Revision Dates

Formerly: PPB-WFBMC-NCBH-95

6/96, 4/99, 4/01, 10/02, 12/02, 7/05, 4/08, 9/11, 3/15, 3/17, 8/18 (updated administrative director information)

Review Date	Revisions	Signature
8/2020	Changed department name to POCT Compliance as necessary; changed section 10c manager name/contact info; changed format of section 11 Review/Revisions/ Implementation and review cycle from 3 years to 2 years; added related procedures as links in Title 21 (section 12); added POCT application as Attachment; changed CAP and TJC dates in section 13b and c; added Revision table at end of procedure	