Wake Forest Baptist Medical Center	Non-Waived Point of Care Testing (POCT) Quality Management Plan and Quality Control/Quality Assurance Procedures PRO-POCT-LAB-18 Previously PPB-WFBMC-LAB-775-18	**Dept: 536**	Point of Care Testing
		Effective Date:	03/1997
		Revised Date:	10/2014
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Signature:			

1) General Procedure Statement:

To ensure quality Point of Care Testing (POCT) results, the Wake Forest Baptist Medical Center (WFBMC) Clinical Laboratory has developed a quality management (QM) plan for non-waived POCT. The POCT QM plan will follow WFBMC quality initiatives, as applicable. To ensure compliance, the POCT program will follow all applicable state and local regulations and the College of American Pathologists (CAP) governing standards. The plan includes quality control (QC), quality assurance (QA), and quality improvement (QI) activities. POCT QM procedures monitor indicators; such as accurate patient identification, test result quality by review of QC records, and compliance with requirements for training and competency of testing personnel. The goal for these indicators is 100% compliance. As necessary, QA reports are generated for user sites.
User sites are encouraged to report and discuss quality and safety issues related to POCT without fear of retribution.

A WFBMC multi-disciplinary POCT committee exists to address POCT issues, including, but not limited to: regulatory concerns, quality issues, or requests for addition of new POCT service.

POCT QM procedures are reviewed biennially by the Clinical Laboratory POCT Medical Director.

The Clinical Laboratory Section Manager for Point of Care Testing and the Point of Care Testing Coordinator have been given designee status by the Clinical Laboratory POCT Medical Director for review of POCT records.

a. Scope/Purpose:

This document establishes procedures and guidelines for assuring quality of Point of Care Testing results and defines current quality management and improvement practices. Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.

b. Responsible Department/Party/Parties:

i. Procedure owner: Clinical Laboratory Point-of-Care Testing Manager/Coordinator
ii. Procedure: Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.
iii. Supervision: The Medical Director for Point-of-Care Testing shall supervise the person(s) performing activities outlined in this document
iv. Implementation: Each applicable POCT site manager is responsible for ensuring compliance with processes stated in this document.

2) Definitions:

a. Point-of-Care Testing (POCT)—defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratory.

b. Non-Waived Tests—Tests of moderate or high complexity as designated by the Food and Drug Administration (FDA)

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

d. Quality Control (QC)—processes to ensure the test system is performing as expected.

i. Quality Control (QC) verifies the performance of the test system. (For example, analyzer performance, reagent/tube/cartridge performance, technique of testing personnel)

ii. Controls are run daily for quantitative and qualitative tests. Follow device/reagent/manufacturer specific procedure(s) for details. Regulatory and accrediting agency requirements must be followed.

iii. QC results are to be evaluated for acceptability, prior to reporting patient results.

iv. There should be documentation of corrective action when control results exceed defined acceptability ranges.

v. Patient testing MUST be discontinued using the effected equipment and reagents, until the problem is resolved and acceptable QC results are obtained.

vi. Control specimens must be tested in the same manner and by the same personnel as patient samples.

e. Quality Assurance (QA)—a system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.

f. Quality Improvement (QI)—activities implemented to improve the quality of processes

g. Proficiency Testing (PT)—Unknown samples sent to a lab/test site by a Centers for Medicare and Medicaid Services (CMS)-approved PT program

h. College of American Pathologists (CAP)—Accrediting agency for the WFBMC Clinical Laboratory. Point-of-Care sites included on the CLIA certificate of the Clinical Laboratory are accountable to standards set forth by CAP.

i. Information Technology and Services (ITS)—medical center-wide department serving the clinical, research and academic enterprise.

j. Electronic Healthcare Record (EHR)--Digital version of a patient's paper medical chart

3) Procedure:

a. Non-Waived Point-of-Care Testing Sites evaluated under this QM plan:

Refer to Appendix A

b. Data Review/QA Activities

i. Daily/Weekly/As Needed

Refer to method-specific procedures for details.

ii. Monthly

- The POCT Coordinator or designee will perform monthly QC/QA review for the locations covered by the Clinical Laboratory CLIA certificate.
- Pre-analytical, analytical, and post-analytical variables will be included as part of the QA process to ensure result quality and safety. A performance report will be issued to the sites, as needed.

- Quality Control (QC) records will be reviewed and initialed each month by the POCT Coordinator or designee. More frequent monitoring will occur as necessary. Site manager or site designee is responsible for reviewing and signing QC records, prior to return to the Clinical Laboratory POCT Coordinator.
- **The following will be assessed, as applicable: (pre-analytical)**
    - Verification that proper instrument identification is included on all QC and maintenance documents.
    - Verification that QC has been performed each day of patient testing.
        - If a device was not used on a particular day for patient testing, it is acceptable to document "not in use" (NIU).
        - All NIU documentation should be initialed by staff member indicating the device was not used.
    - Verification that all QC results are within acceptable limits and appropriate troubleshooting and follow-up action taken for QC outliers.
    - Verification that all required maintenance has been performed.
    - As applicable, Clinical Engineering repair reports will be reviewed.
    - QC reagents and testing reagents will be checked for expiration date.
    - Tubes/cartridges will be checked for QC validation, prior to patient use.
    - If applicable, new lot numbers of QC material will be tested in the laboratory for range verification. For additional details, refer to document, "ACT Quality Control Range Verification as Performed by the Clinical Laboratory".
    - If applicable, POCT reagent storage refrigerator temperature records will be reviewed.
    - New employees who need training should be identified. It is the responsibility of the POCT user site manager to ensure that all users are trained and certified prior to performing patient testing. The POCT user site manager should forward up-to-date user lists to the POCT Coordinator periodically.
    - Non-compliance with above-stated items will be addressed on an individual basis and documented, as appropriate.

    - **i-STAT Quality check (QC) codes and star out** rates will be monitored. **(analytical)**
        - QC codes should not exceed 5% each month
        - Star out rate should not exceed 2% each month.
        - Failures of these limits will be investigated by the Clinical Laboratory POCT Coordinator.
- **i-STAT Monthly Liquid QC**
  Liquid QC will be performed for each i-STAT test by various i-STAT user sites. Results should be within acceptable tolerance limits. QC will be rotated among different i-STAT users.
- **Quality Assurance Reports:** As needed, QA reports are generated to monitor compliance rates of POCT user sites. In addition, the WFBH Patient Safety Net/RL6 is used, as needed. Incidents reported to this site include:
    - i-STAT sample mis-identifications
    - Non-compliance with QC policies and procedures
    - Unauthorized use of POCT equipment
    - Other incidents, as needed
- **Quality Indicators Reported to the Department of Pathology Quality Assurance Team**
    - Compliance with quality control (QC) procedures (pre-analytical)
        - Expected Performance: 100% compliance
        - Unacceptable Threshold: <95%

- Sample Mis-identifications (pre-analytical/post-analytical)
  - Expected Performance: Target is 0% misidentified samples
  - Unacceptable Threshold: >0.2%
- Proficiency Test Results (analytical)
  - Expected Performance: Target is 100% of the PT values to be within acceptable tolerance limits.
  - Unacceptable Threshold: Less than 80% of the values within acceptable limits and/or subsequent failures of the same analyte across PT events.
- Unauthorized use/off-label use of POCT equipment or supplies (analytical)
- Device-related adverse patient events (analytical)
- Employee or clinical provider concerns related to test quality or safety (post-analytical)
- Other, as needed

iii. <u>Bi-Annual QA Activity</u>

- **Analyzer and Methodology Comparison**
  - As applicable to the methodology, user sites which have duplicate analyzers should perform a sample comparison between analyzers to verify agreement at least twice per year.
  - As appropriate, POCT analyzers are also compared against the Clinical Laboratory analyzers to verify agreement of test results.
    - I-STAT methodology is compared against Blood Gas Lab methodology and Clinical Laboratory methodology, as appropriate.
    - AVOX analyzers are compared against one of the Blood Gas Lab co-oximeters.
    - ACT user sites, which have multiple analyzers, perform comparisons amongst analyzers to verify agreement of results.
    - ACT proficiency results for all test sites are compared, once final evaluation reports are received from CAP. Results are not compared, prior to deadline for submission to CAP.
    - WFBMC sequesters lot number of Hemochron HRFTCA510 ACT tubes to also ensure comparability of results across test sites.
  - **Comparison results should agree**…
    Acceptable limits were established utilizing the CAP proficiency testing participant summary evaluation criteria as a guide and under the direction of the POCT Medical Director.
    - +/-10% for **ACT,** provided same method and clot **a**ctivator is used.
    - +/- 1g/dL for THb and +/-3%HbO2 (**AVOX)**
    - pH--0.04
    - pCO2--5 mmHg or 8%, whichever is greater
    - pO2--10% if analyzers are side-by-side during testing--+/-20% if testing not performed 'side-by-side'
    - Potassium--0.5 mmol or meq/L
    - Sodium--4 mmol or meq/L
    - Ionized calcium--0.1 meq/L
    - Hemoglobin--1 g/dL
    - Hematocrit--3%
    - Creatinine--0.3 mg/dl or 15%, whichever is greater
    - Lactate--20%
    - INR--+/- 0.4 or +/- 20% if INR above 4
    - Glucose--+/-6 mg/dl or 10%, whichever is greater
    - Chloride--+/-5 %
    - BUN--+/-2 mg/dl or 9%, whichever is greater

        - Measured Total CO2--10%
        - Other analytes may be added as necessary. Limits of acceptability will be established/approved by the POCT Medical Director at the time of implementation
    - Results should be forwarded to the Clinical Laboratory, Point of Care Testing Coordinator's office for review.
    - See Appendix A for a listing of sites, which have multiple analyzers for the noted test.
    - The i-STAT Technical Bulletin, "Proficiency Testing on the i-STAT System" states, "All analyzers that pass the Electronic Simulator test are equivalent". Therefore, individual i-STAT handheld devices will not be compared against each other. The i-STAT methodology will be compared against appropriate Clinical Laboratory methods.
- **Calibration/Calibration Verification:**
    - **i-STAT Calibration Verification**
      Performed on the i-STAT analytes, with the exception of coagulation tests, each 6 months, using a manufacturer-provided calibration verification kit. The kit consists of 5 levels of tests material that is tested in singlet. Manufacturer instructions are followed. Results should match insert values. Follow-up and corrective action is taken, as needed.
      Note: i-STAT cartridges are calibrated by the manufacturer. Calibration is 'controlled' by software upgrades issued by the manufacturer. Other on-site calibration options are not available.
    - **AVOX Calibration Verification**
      Performed daily, weekly, and every 6 months. A linearity kit can also be used to verify calibration. Refer to AVOX procedure for details.
- **i-STAT Thermal Probe Check**
  Thermal probes should be checked at least twice per year. Refer to the i-STAT System Manual for instructions.
- **Analytical Measurement Range (AMR)**
  Upper and lower limits of the AMR for all measured analytes are defined. Results falling outside of these limits are appropriately reviewed and retested, if necessary, before reporting. Manufacturer instructions are followed for validation of AMR.
    - **AVOX AMR**
      Validated every 6 months, as part of the calibration verification procedure.
      Manufacturer instructions are followed for validation of AMR.
      Results should fall within the limits of acceptability included in the package inserts of the calibration verification material.
      When new instruments are placed into service or following maintenance/repair, AMR will be validated.
    - **i-STAT AMR**
      Validated every 6 months, as part of the calibration verification procedure.
      Manufacturer instructions are followed for validation of AMR.
      Results should fall within the limits of acceptability included in the package inserts of the calibration verification material.
      When new instruments are placed into service, AMR will be validated.
    - **AMR Validation Coagulation Tests**
      AMR validation is not necessary for coagulation tests.

iv. <u>Annual QA Activities</u>

Annually, interfaced POCT result reports will be sent to the Medical Director for review and approval. The Medical Director will review and approve patient reports annually to verify content and format of the reports. Refer to the Laboratory General CAP checklist for additional requirements pertaining to patient report review.

v. <u>As Needed, Quality Assurance</u>

- **Acceptability of New Reagents**

- New test reagents will be checked for acceptability, prior to patient use, by performing liquid quality control checks. Confirmation will be made that patient reference and action ranges are not affected by the implementation of new test reagents.
- Liquid quality control values should be within acceptable limits, prior to patient use.
- QC values should read similar to the QC values obtained on the previous lot number of reagents to ensure that patient results are similar.
- Any reagent which fails liquid quality control checks should **not be used for patient testing, until a resolution is made.** The manufacturer can be contacted for assistance, if liquid QC checks fail after 2 repeats and no cause is identified.

- **Reagent Labeling and Handling**
  - POCT sites will follow applicable manufacturer, regulatory, and Clinical Laboratory procedures related to reagent and product labeling.
  - Reagents, calibrators, cellular controls, and solutions will be properly labeled, as applicable and appropriate, with the following elements:
    - Content and quantity
    - Concentration or titer
    - Storage requirements
    - Date prepared or reconstituted by the laboratory or POCT site
    - Expiration date
    - Other labeling, as required by regulatory authorities
    - The laboratory must assign an expiration date to any reagents and media that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions, and risk of deterioration.
- **Reagent Kit Components**

  If there are multiple components of a reagent kit, POCT sites will use components of reagent kits only within the kit lot, unless otherwise specified by the manufacturer.

  If applicable, written documentation will define allowable exceptions for mixing kit components from different lots.
- **Installation of New Methodology**
  - The Clinical Laboratory Medical Director for POCT will approve all new POCT methods/equipment, prior to live patient testing. The Medical Director's signature on validation records/reports indicates approval of the test device for patient use, unless additional verbiage indicates otherwise.
  - For methods implemented after June 15, 2009, the method validation should include:
    - A summary statement, signed by the laboratory director (or designee who meets CLIA director qualifications), documenting review of validation studies and approval of each test for clinical use. An example of such a statement is: "This validation study has been reviewed and the performance of the method is considered acceptable for patient testing."
    - The summary statement must include a written assessment of the validation/verification study, including acceptability of the data.

  - For FDA-cleared/approved tests, a summary of the verification data mush address analytic performance specification, including analytic accuracy, precision, interferences, and reportable range, as applicable.

  - Prior to implementation of new point-of-care testing methods: precision, accuracy, linearity, reportable range, reference range and interfering substances may be validated/investigated by the following methods, as applicable:

- Repeat testing of 2 levels of liquid quality control material.
  - Mean, standard deviation and coefficient of variation should be calculated and should agree with manufacturer's claims.
- Patient comparison samples will be tested against current in-house methodology.
- Manufacturer information may be used to evaluate precision, accuracy, reportable range, reference range, linearity, sensitivity and interfering substances.

- The Clinical Laboratory Medical Director for Point-of-Care Testing will review validation procedures for each installation.
- Under certain circumstances, daily controls may be limited to electronic/procedural/built-in controls, provided appropriate validation studies are performed. Refer to current CAP POCT/Lab General/All Common checklists for additional details.

- **Method Performance Specifications Availability**
  The laboratory's current test methods, including performance specifications and supporting validation data (analytic accuracy, precision, analytic sensitivity, interferences, reference range, and reportable range, as acceptable), are available to clients of the laboratory and to regulatory inspection teams upon request. The laboratory will also provide data on clinical validity, if available, to clients upon request.
- **Analytic Methodology Changes**
  If the laboratory/point of care test site changes its analytic methodology, so that test results or their interpretations may be SIGNIFICANTLY different, the change is explained to clients.
- **Analyzer Validation Post-Repair**
  To verify performance, analyzers which are returned from manufacturer or Clinical Engineering repair, should have acceptable/applicable electronic and acceptable/applicable liquid quality control performed. Verification should be completed prior to release of the device for patient use. Prior to patient use, i-STAT and Hemochron Response analyzers should have appropriate programming entered into the analyzer, as noted below.
  - **i-STAT**
    - Verify the current date, time, JAMS, and CLEW are programmed into the analyzer.
    - Appropriate WFBMC configuration should also be programmed, via the I-STAT data management system.
    - Unit should be set to the appropriate resulting panel.
    - The electronic simulator should be tested and should pass successfully.
    - The barometric pressure (BP) should be verified against the ICU Blood Gas Lab barometer. The i-STAT BP should compare with the barometer +/- 6 mmHg.
    - The thermal probe check should be completed. Refer to I-STAT System Manual for instructions.
  - **Hemochron Response**
    - Verify Date and Time
    - Set-up user PIN in analyzer
    - Require valid user PIN entry
    - Require electronic QC every 8 hours
    - Require patient ID entry
    - Set 911 attempts to 0 for each test well. Some sites may require exception to this rule, as necessary.
    - SAVE ALL ENTERED INFORMATION IN THE ANALYZER. RE-VERIFY THAT SETTINGS ARE CORRECT.
    - Perform both levels of Electronic QC on each test well-obtain acceptable results.
    - Perform 2 levels of liquid QC on each test well-obtain acceptable results.
    - Complete ACT liquid and electronic QC logs in the ACT QC logbook. Records should indicate that QC was performed for post-analyzer repair.

- **Detection of erroneous, spurious, or unusual laboratory results**

  There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

  Examples of such processes include, but are not limited to:

  - Daily i-STAT critical value report
  - As needed, Hemochron Response data manager review for abnormally low (<80 second) or abnormally high (>600 second) results
  - Medtronic HMS Plus data manager review
  - Random patient chart audits, included as part of annual competency

- **Product Recall**

  If a product recall occurs, which is related to currently used POCT equipment or reagents, the Clinical Laboratory POCT Medical Director will be notified and will determine an appropriate action plan. All actions will be appropriately documented. See Appendix B for 'Product Recall Documentation Form'. Whenever patient results have been reported using the recalled product, the ordering physician should be notified about the recall specifics.

- **Device Related Adverse Patient Events**

  In the event of an adverse patient event related to POCT equipment, the incident will be reported to the site manager, patient physician, POCT Coordinator, Clinical Laboratory POCT Medical Director, WFBMC Risk Management, the device manufacturer and FDA, as applicable. All actions will be coordinated with the Clinical Laboratory POCT Medical Director.

- **Critical Equipment Incidents**

  Critical equipment incidents will be reported on the POC monthly QA reports. This includes any incident involving an instrument that could cause problems or delays in patient care. These could be from the instrument itself or from user error.

- **Employee Concerns Regarding Test Quality and Safety**

  Should employees have concerns regarding POCT result quality or safety, the concerns should be reported to the site manager, POCT Coordinator, Clinical Laboratory POCT Medical Director, or the WFMBC Patient Safety Net/RL6. Concerns, which are not adequately addressed, can be confidentially reported by the employee to the College of American Pathologists (CAP) at 1-866-236-7212.

- **Employee and Physician Satisfaction**

  All suggestions from within or outside the Department of Pathology for additions or improvement in the services offered will be reviewed. Requests for adding point-of-care testing service must be submitted to the WFBH POCT Committee. Complaints, problems, and issues communicated to the POCT section will be reported on the monthly POCT QA report(s), along with a summary of follow-up action taken.

- **Point-of-Care Testing Interface Downtime**

  If the POCT interface or data management system becomes temporarily non-functional, appropriate measures will be taken to ensure that results are posted to the electronic health record (EHR). Patient treatment and care would not be affected by such a downtime. Patient care staff members have immediate access to the results on the handheld analyzer. POCT analyzers retain results in memory.

  During an extended downtime, I-STAT handheld analyzers may be swapped to avoid loss of data to the EHR. When interface communications are restored, the data will be downloaded to the EHR. Hardware is monitored by ITS for performance.

  The system will alarm in the event of a server failure.

- **i-STAT Data Management System Back-Up**

  The i-STAT data management system is backed up nightly to the WFBMC ITS network.

- **i-STAT Data Management Support**

  If support is needed:
  --Contact the WFBMC Help Desk (6-HELP)
  --Contact i-STAT Tech Support (1-800-366-8020)
  --Contact Abbott Tech Support (1-877-529-7185)
- **Proficiency Testing**
  - The POCT program will participate in appropriate proficiency testing programs to ensure quality of test results.
  - As needed, proficiency material will be dispersed to all POCT sites, completed by POCT testing personnel, and returned to the Clinical Laboratory POCT office for submission to CAP for evaluation.
  - The testing procedure included with the proficiency testing material will be followed for proficiency sample handling, analysis, and result reporting.
  - All PT samples in the kit should be tested on the Same Day.
  - One staff member should test All samples that come in the survey kit. (referenced as PT event)
  - Testing of PT events should be rotated among testing personnel each calendar year, as available.
  - A goal, but not a requirement, is to follow this rule, at least one PT event-- per year-- per staff member when possible. Managers will keep track of personnel testing PT samples to make sure that one person is not always performing the PT events.
  - One analyzer should be used to test all samples that come in a survey kit. (referenced as PT event)
  - A PT event should be handled as would a patient sample, so analyzer selection should be as if it were a patient sample in the workflow. Neither the laboratory nor site managers should dictate which analyzer is used for testing of PT samples. It would be at the discretion of the testing staff member, when this is the workflow for patient samples.
  - NOTE: There is no communication, regarding proficiency results, between the Clinical Laboratory and between testing sites until after the proficiency testing is completed and evaluated by CAP.
  - Inter-laboratory communication about proficiency testing results is prohibited before the deadline for submission of data has passed.
  - Communication amongst point of care test sites regarding results is prohibited until after the deadline for submission of results.
  - Proficiency testing samples will not be referred to any site other than the specified POCT site.
  - The Point of Care Testing Coordinator and Clinical Laboratory POCT Medical Director will review proficiency results.
  - The attestation statement will be signed by the Clinical Laboratory POCT Medical Director.
  - Failed proficiency testing results will be evaluated for appropriate resolution action and documentation noted. Investigation into proficiency sample failures will include review of quality control performed for that day and for the reagents used in proficiency testing. Testing personnel training and competency assessment will be verified. Proficiency sample handling will be investigated as a possible cause of the failure. All investigative actions will be documented.
  - The Clinical Laboratory POCT Medical Director will review proficiency result failures and investigation documentation.
  - Proficiency results will also be evaluated for bias or trending. Any follow-up action taken will be documented on the CAP result report.
  - **Non-Evaluated Results:** If proficiency results were not evaluated by CAP, due to lack of consensus, or because the results were submitted after the cut-off date, or the results were reported incorrectly to CAP, they will be compared against the results published by CAP included

with the CAP report. This will verify acceptable proficiency performance by WFBMC point of care testing sites.

- Primary records related to PT and alternative assessment testing are retained for two years (unless a longer retention period is required elsewhere in other regulations). These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and documentation of follow-up/corrective action.

- **Proficiency Testing for Analytes not Covered by CAP Proficiency Testing**
  - An acceptable program will be established at the direction of the Clinical Laboratory POCT Medical Director.
  - NOTE: There is no communication regarding proficiency results between the Clinical Laboratory and test sites until after proficiency testing is completed and evaluated. Failed proficiency testing will be evaluated for appropriate resolution action and documentation noted on the records.
  - The Clinical Laboratory POCT Medical Director will review proficiency failures.
- **Intermittent Testing**
  - Tests that are taken out of production for a time is considered to be taken out of production when (1) patient testing is not offered AND (2) PT or alternative assessment, as applicable, is suspended.
  - When a test is put back into production, the following requirements must be met:
  - PT or alternative assessment performed within 30 days prior to restarting patient testing
  - Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing
  - Competency assessed for analysts within 12 months prior to restarting patient testing.
- **Thermometric Standard Device**
  - An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards or traceable to NIST standards) is available and used when necessary.
  - Thermometric standard devices must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration, or they are subject to CAP requirements for non-certified thermometers.
  - Thermometers should be periodically evaluated for damage. Thermometers with obvious damage should be rechecked for continued use.
  - The Clinical Laboratory maintains NIST-verified thermometers. Annually, the NIST thermometers are checked by WFBMC Clinical Engineering and a verification statement is issued for the device.
  - The Medtronic HMS thermometer is issued a certificate by the manufacturer. No expiration date is indicated.
  - **Non-certified Thermometers**

    All non-certified thermometers in use are checked against an appropriate thermometric standard device before initial use and as defined by laboratory policy.

    If digital or other displays of temperatures on equipment are used for daily monitoring, the laboratory must verify the readout is accurate. The display must be checked initially and following manufacturer's instructions.
- **Document Control**

  Policies/Procedures/Guidelines
  - All current POCT policies/procedures/guidelines for use of equipment will be made available to each POCT user site. These documents are posted on the WFBMC Intranet Point-of-Care Testing web site.
  - Content will be compliant with CAP standards for required elements of procedures. Refer to CAP standards for details.

- Discontinued policies/procedures/guidelines will be kept for a minimum of 2 years.
- Documentation of review by POCT users will be included as part of the initial training process. It will also be included as part of the yearly competency evaluation process.
- The Laboratory CLIA Director and Clinical Laboratory POCT Medical Director, prior to implementation in patient test sites, will approve all POCT policies/procedures/guidelines and major modifications to POCT policies/ procedures/guidelines.
- All POCT policies/procedures/guidelines will be reviewed and signed biennially by the Clinical Laboratory POCT Medical Director.
- A listing of current POCT policies/procedures/guidelines can be found in the "Point of Care Testing- Policy and Procedure Summary".

o **Record Retention**

- The following records must be retained for at least 2 years:
  - Specimen requisitions (including the patient chart or medical record only if used as the requisition)
  - Patient test results and reports
  - Instrument printouts
  - Accession records
  - Quality control records
  - Instrument maintenance records
  - Proficiency testing records
  - Quality management records
  - Manual computer entry of patient result data from worksheets, print-outs, etc. requires retention of all worksheets, printouts, etc. for at least two years.
  - For results that are manually entered into the computer from 1) observation of an electronic display, with no paper print-out available, or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer.

- Instrument maintenance records may be retained for longer than the 2-year requirement (e.g. for the life of the instrument), to facilitate troubleshooting.
- Records of method performance specifications must be retained while the method is in use, and for at least two years afterwards.
- For data directly transmitted from instruments to the laboratory computer system, via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., so long as the computer retains the data for at least two years.
- For requirements on retaining records of changes to software, the test library, and major functions of laboratory information systems, please refer to the Hardware and Software section of the Laboratory Computer Services section of the CAP Lab General Checklist.
- In the event the laboratory ceases operation, all records will be retained and available for the appropriate times.
- Current and applicable regulatory or accrediting agency standards will be met.

- **Specimen Retention**
  - Specimens of serum, heparinized plasma, EDTA plasma, CSF, and body fluids (except urine) should be retained for 48 hours. The 48 hour retention requirement does not apply to whole blood samples; for example, samples collected for blood gas testing.
  - Urine specimens should be retained for 24 hours; exceptions may be made at the discretion of the laboratory director.
  - Blood films, permanently stained body fluid slides, and permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles) should be retained for 7 days.
  - Specimens must be kept under appropriate storage conditions.

- **Health Insurance Portability and Accountability Act (HIPAA)**
  - The WFBMC POCT program will follow HIPAA regulations and requirements to protect patient confidentiality.
  - Appropriate measures will be taken to avoid disclosure of protected health information to unauthorized personnel.
  - In regards to HIPAA, the POCT program will follow policies and procedures established by WFBMC.
  - **i-STAT**
    - Whenever an i-STAT user is terminated or no longer uses the i-STAT test device, the user site supervisor should notify the POCT office. Staff members of the POCT office will remove testing access from applicable i-STAT data management systems.
    - Access to the i-STAT data manager is password protected and electronically documented.
    - Access for any individual is specifically programmed into the system by a staff member from the POCT office.
    - The i-STAT data management system can be viewed for a current list of users who have access.

  - **Hemochron Response and Medtronic HMS Plus**
    - Whenever a Hemochron Response or Medtronic HMS Plus user is terminated or no longer uses the device for patient testing, the user site supervisor should notify the POCT office and delete the user's access from the test device user database.
    - It is the responsibility of the user site manager and/or POCT user site coordinator to ensure accurate operator database information.
  - **Other POCT Equipment with Operator ID and Patient ID Entry**

    Should any new POCT equipment be purchased or added to the Clinical Laboratory POCT menu, WFBMC and ITS policies will be followed to ensure patient confidentiality.
  - **Analyzers Returned to Manufacturer for Repair**

    Any analyzer/system that is sent outside the WFBMC facility will have the database cleared if patient information is included in the database. In the event that patient data cannot be cleared prior to return to the manufacturer, the manufacturer has signed a Business Associate agreement with WFBMC to address HIPAA concerns.

- **Verbal Critical Result and Verbal Orders "Read Back"**
  - All POCT sites should follow the WFBMC policy for "read back" of critical results and verbal orders.
  - Critical Results of Tests and Diagnostic Procedures, formerly PPB-NCBH-10, should be followed regarding read back of verbally reported critical values.

- Anytime an order or critical result is verbally reported, re-back should occur to ensure accuracy of results. Documentation of read-back should occur.

- **Documentation of Critical Result Notification**
  - Critical results are test results that fall outside high and low critical limits, which define the boundaries of life-threatening values for a test.
  - Critical results represent an emergency condition and should be reported immediately to the patient's attending physician, nurse, or mid-level provider.
  - All critical results reported by point-of-care testing devices that do not routinely get reported to an authorized clinical provider—physician, nurse, or mid-level provider—must be notified within 15 minutes of result availability. Documentation of notification should occur.
  - Documentation of notification should be noted in the patient record.
  - Documentation should include:
    - Notifying individual's initials/signature
    - The critical result
    - Notifying Date
    - Notifying Time
    - Name of the person that is notified of the critical value
  - The author's name should be legible and authenticated.
  - Documentation pertaining to the person that is notified of the critical value should be identifiable for future questions.
  - At a minimum, last name and credentials should be documented. It is preferred that the full name of the provider be documented.
  - Critical values should be properly evaluated with the patient's clinical symptoms and followed-up by necessary laboratory confirmation.
  - Any unexpected result should be repeated on the i-STAT or sent to the laboratory for confirmation.
  - **Quality Assurance**
    Compliance is monitored by POC test sites.
    - Audit of patient testing is performed for each POCT staff member, as part of annual competency assessment.
    - The audit is performed to ensure critical values are notified and documented within the defined critical value notification threshold.
    - Expected performance is 100% compliance.

- **Employee Training and Competency Assessment**
  - A copy of diploma or transcript must be on file for each staff member that performs non-waived point-of-care testing.
  - Individuals that have received all of their education outside of the United States must have documented education equivalency in their personnel file.
  - Records will be maintained, documenting that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job.
  - The records will show that training specifically applies to the testing performed by each individual.
  - Training documentation, regarding specimen collection techniques will be maintained.
  - Retraining and reassessment of competency must occur when problems are identified with employee performance.

- Testing personnel are required to score at least 80% correct on written competency assessment and must be deemed 'competent and can perform independently' on the competency observation.
- Competency may only be assessed by an authorized individual meeting the qualifications of Technical Consultant, as defined by CLIA 42 CFR §493.1411.
- Competency will be assessed at the following intervals:
    - Following training and before the staff member performs patient testing
    - 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
- Elements of Competency
    - Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.
    - Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
    - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
    - Direct observation of performance of instrument maintenance and function checks, as applicable
    - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
    - Evaluation of problem-solving skills
- **Patient Chart Audit**
  As a component of annual competency, patient records will be audited to verify proper documentation of patient results. This will include the result, date, time, units of measure, critical value notification, if applicable, and documentation of the person performing the test. A clear audit trail should be established to determine testing personnel, reagents and analyzer used for testing. An audit confirming documented physician order for the test will also be completed. If documentation is not complete, the user site manager/designee should counsel the employee. Follow-up action will be taken as necessary. (e.g. credit of testing that has no documented provider order or follow-up action for notification/documentation of notification of a critical value)

- **Arterial Punctures**
    - Personnel performing arterial punctures should be knowledgeable about the more significant complications of this procedure compared with a venipuncture.
    - The Department of Respiratory Care is responsible for maintaining training/education/competency documentation for staff that collect blood gas specimens.
    - If staff members from other disciplines perform arterial punctures, the applicable department is responsible for maintaining records of training/education/competency.

- **Blood Gas Testing**
  - **Test for Collateral Circulation**
    - For radial artery sampling, a test for collateral circulation is performed and documented before arterial puncture, as applicable.
    - The site from where the sample was obtained should be documented.
    - Clinical sites performing radial artery punctures are responsible for defining situations that require testing for collateral circulation. Preferred technique should be identified.

  Documentation of Test for Collateral Circulation (Allen's Test) Monitoring
    - At a minimum, bi-annually, Respiratory Care will complete a random chart audit of at least 10 patient records to document compliance with performance/documentation of the Allen's Test.
    - The report will be provided to the Clinical Laboratory for review.
  - **Ambient Air Contamination**
    - A system will be in place to prevent ambient air contamination.
    - All specimens collected for blood gas analysis should be free of air contamination and capped Immediately after sample collection.
    - At the time of collection and at the time of testing, samples should be handled in a manner to avoid air contamination.
- **Safety**

  Follow all WFBMC Infection Control policies and procedures.
  - **Standard Precautions**—Hand Hygiene

    Standard precautions are used for point-of-care testing by testing personnel. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between each patient contact, according to Standard Precautions.
  - **Single-Use Capillary Stick Devices**
    - Only auto-disabling single-use capillary stick devices will be used for collection of blood samples for point-of-care testing.
    - Single-use devices should only be used for one patient.
  - **Disinfection of Point-of-Care Test Devices/Analyzers**
    - All POCT analyzers should be disinfected between each patient use.
    - Follow all manufacturer guidelines.

4) 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. All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director or section manager.

b. Office of Record: Clinical Laboratory, Section on Point-of-Care Testing

5) Related Policies/Procedures/Guidelines:

a. "Point of Care Testing Using the i-STAT Analyzer System"

b. "Activated Clotting Time (ACT) Determination at Point-of-Care Testing Sites Using the Hemochron Response ACT Timer System"

c. "ACT Quality Control Range Verification as Performed by the Clinical Laboratory"

d. " Oxyhemoglobin and Total Hemoglobin Measurement Using the AVOXimeter 1000E Analyzer"

e. " HMS Plus Hemostasis Management System Version 4.0"

f. "Quality Assurance Plan Point of Care Testing" PLAN-POCT-LAB-101

g. "Documentation of Foreign Equivalency for Laboratory Testing Personnel" Lab Admin 11
h. "Clinical Laboratory Point-of-Care Testing Competency Assessment for Non-Waived Testing" POL-POCT-LAB-24
i. "Proficiency Testing Procedure" Lab Admin 3

6) References:

a. 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 4/21/2014
b. College of American Pathologists (CAP) Proficiency Testing Participant Summary--AQ Survey 2014, CAP, 325 Waukegan Rd, Northfield, Illinois 60093-2750, Revised 4/21/2014

7) Attachments:

a. Appendix A--Non-Waived POCT Sites and Sites with Multiple Analyzers
b. Appendix B--Product Recall Documentation Form

8) Revised/Reviewed Dates and Signatures:

Document Adopted: 4/10/97
Revised:
10/99
04/22/01
06/20/02
01/23/03
10/22/03
06/09/04
05/06
3/08
07/09
5/2010
11/2010
8/2011 (renamed using WFBMC rather than NCBH)
2/2013
10/2014 (renumbered to PRO-POCT-LAB-18)

Biennial Review: _____ Date: _____

Biennial Review: _____ Date: _____

Modifications/Date/Reviewed/Approved: