Wake Forest Baptist Medical Center	Activated Clotting Time (ACT) Determination at Point-of-Care Testing Sites Using the Hemochron Response ACT Timer System PRO-POCT-LAB-10 Formerly PPB-WFBMC-LAB-775-10	**Dept:**	Point of Care Testing
		Effective Date:	06/1996
		Revised Date:	07/2016
		Contact:	Department of Pathology Clinical Laboratory Section on Point-of-Care Testing
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Signature/Date:			

I. General Procedure Statement:

The Clinical Laboratory at Wake Forest Baptist Medical Center (WFBMC) is responsible for overseeing all explicitly identified non-waived laboratory testing (as defined by the Clinical Laboratory Improvement Act) (CLIA) performed in clinical areas by non-laboratory personnel. Specific testing sites have been identified and included under the CLIA 88 certificate of the WFBMC Clinical Laboratories for a highly complex laboratory. Testing policies and procedures must meet all regulatory guidelines established by CLIA and the accreditation standards established by the College of American Pathologists (CAP). This document is to ensure that all lab testing is performed according to manufacturer's recommendations and that each employee follows the same quality control and patient testing procedures. The Hemochron Response Operator's Manual, Quality Control (QC) and ACT tube package inserts can be referenced for additional information not included in this procedure.
All ACT testing should have a documented physician order or follow a documented protocol.

A. Scope:

This document establishes procedures and guidelines for assuring quality of Point-of-Care Testing (POCT) results obtained from the Hemochron Response test device. Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.

1. **Responsible Department/Party/Parties:**
   - a. **Procedure Owner:** Clinical Laboratory Point-of-Care Testing Manager/Coordinator
   - b. **Procedure:** Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.
   - c. **Supervision:** The Medical Director for Point-of-Care Testing shall supervise the person(s) performing activities outlined in this document.
   - d. **Implementation:** Each applicable POCT site manager is responsible for ensuring compliance with processes stated in this document.

II. 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 FDA.

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

D. 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.

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

F. **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.

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

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

I. **Technical Limits/Reportable Range/Analytical Measurement Range (AMR):** The range at which the analyzer has been verified to obtain accurate results. Each method-specific analyte has a specific reportable range.

J. **Normal (Reference) Range:** The range of values for the average patient population.

K. **Erroneous:** containing error, mistaken, incorrect, wrong

L. **Analyzer/Device**: For the purposes of this document, refers to Hemochron Response instrument

III. Principle:

Whenever blood is exposed to a foreign surface, the clotting process is triggered. Under such circumstances, low to high levels of heparin anticoagulation are required to prevent thrombosis. The Activated Clotting Time (ACT) is a quantitative in vitro test that monitors heparin anticoagulation by the clotting time of the patient sample during various medical procedures. The Hemochron ACT demonstrates linear correlation to the anticoagulation effects of heparin between 0.0 and 3.0 units/cc of blood if using P214 ACT tubes. **Different tube types CANNOT be interchanged. ACT results will differ between different tubes made by the same manufacturer. ACT methods may also vary in results reported. EXTREME caution should be taken if there is a need to switch between ACT methods. (For example, Hemochron to Medtronic to i-STAT) Refer to manufacturer literature for information not discussed in this procedure.**

Fresh whole blood is added to a test tube containing an activator and timed for the formation of a clot. The test tube is inserted into a Hemochron instrument and mechanical detection of a fibrin clot in the blood sample automatically terminates the test causing the instrument's digital timer to display the coagulation time in seconds. The mechanism consists of a precision aligned magnet within a test tube and a magnetic detector located within the test well. Following insertion of the test tube containing a whole blood sample, into the well, the magnetic detector senses a magnet within the test tube, as the tube slowly rotates. When the clot begins to form, it causes the magnet to lift within the tube. Since the magnet has been displaced, it is no longer sensed by the instrument's magnetic detector. The instrument gives an audible beep and displays the coagulation time. This is the Activated Clotting Time (ACT) and is reported in seconds.

IV. Procedure

A. Reagents, Supplies

Hemochron ACT test tubes are used for this test. The tube type must be chosen that is consistent with patient therapy. Tubes are stable when stored at room temperature (15-30°C) and used prior to package expiration date on the carton case. Hemochron tubes should not be exposed to temperatures in excess of 37°C. The expiration date should be checked before each use and any expired tubes should be discarded in an appropriate sharps container.

NOTE: All reagents and supplies should be noted with a date received, date quality control checks performed/date opened and product expiration date on the outside of the container.

1. **P214 Tubes**
   a. Contains glass beads as the activator
   b. Non-evacuated
   c. Stamped with a lot specific expiration date
   d. Plastic flip top tubes
   e. Used for monitoring low to moderate therapeutic levels of heparin therapy, up to 3.0 units/ml.
   f. Useful with hemodialysis, hemofiltration, ECMO, and other procedures where low-level heparin anticoagulation is administered.

B. Equipment

1. Hemochron Response ACT Timer.
    - Analyzer, power cord and EQC probe should be handled using Standard Precautions to avoid accidental exposure to blood and body fluids.
    - Clean with WFBMC approved disinfectant when contaminated with blood or body fluids and between each patient.
    - Also, see safety section.

NOTE: Tubes should only be rotated clockwise in the Hemochron analyzers.

2. (2) Unheparinized syringes (1 or 3 ml)
3. Personal Protective Equipment: Gloves
   Note: Gloves should be worn during sample collection, ACT testing, and anytime the analyzer or QC products are handled.
4. WFBMC approved biohazard sharps container

C. Safety

1. All blood samples, analyzers, power cords, QC devices and materials, and used tubes should be treated as biohazardous and handled with care.
2. Standard precautions should be taken to avoid accidental exposure.
3. Sharps (syringes with needles, liquid quality control material and used/discarded tubes) should be disposed of in a biohazard sharps container.
4. Gloves should be worn during sample collection and analysis.
5. Liquid quality control material should be treated as potentially infectious and handled using Standard Precautions.
6. When performing p214 Hepcheck liquid QC, the protective plastic sleeve should be used to cover the QC vial, prior to breaking the ampule.
7. Any device that is contaminated with body fluids should be handled using Standard Precautions and cleaned with a fresh 1:10 dilution of bleach or other WFBMC-approved disinfectant . Do NOT use strong cleaning solutions. They may deform the instrument's plastic components. Routine cleaning is recommended for infection control purposes.
8. Hemochron Response analyzers should be disinfected between each patient use. Use WFBMC-approved disinfectant and follow all WFBMC Infection Control policies and procedures. Carefully, follow instructions and warnings on disinfectant solutions.
9. The transfer of blood to the flip top ACT test tubes from a syringe should be performed using a needleless system. The flip top stopper should be opened completely to dispense the blood specimen and closed completely before shaking.
10. A two-hand technique should be used when transferring blood. One hand should securely hold the tube while the second hand dispenses the blood specimen.
11. The flip top stopper should NOT be pierced by a needle or sharp object, due to the danger of slipping off the flip top and piercing the finger.
12. Do NOT force a tube into the instrument. If resistance to insertion is encountered, gently remove the tube and examine the test well. Remove any obstruction before attempting further use of the instrument.
13. The p214 test tubes contain glass particles. Do NOT handle aerosol or ingest particles.
14. If room temperature is excessively warm (above 37°C), the performance of the Hemochron instruments and tubes could be affected. Appropriate quality control and temperature checks should be performed on the analyzer and tubes to verify performance prior to patient use. Manufacturer technical assistance can be contacted by calling 1-800-631-5945.

D. Specimen Collection and Handling-Gloves should be worn

1. **Patient Preparation**: None
2. Prior to collecting any ACT specimen, the patient's identity should be verified by the WFBMC identification bracelet. 2 patient identifiers should be used. Follow Medical Center policies.
3. If the ACT is tested away from the bedside, blood samples should be identified/labeled in the presence of the patient. Follow all applicable Medical Center policies.

4. The patient medical record number should be entered into the Hemochron Response for identification. Patient identity should be verified throughout entire test process, from sample collection to sample testing, to result reporting.
5. Testing site departmental guidelines should be followed for specimen collection procedures.
6. Fresh whole blood (collected in a collection device **without** anticoagulant) is the required specimen type. Specimens should be processed and tested immediately due to the nature of the sample and test.
7. **Sample Collection for P214 ACT TEST TUBES:**
   a. **For P214 tubes:** use a 1cc or 3cc syringe.
   b. Adhere to the appropriate technique below: **As applicable, follow department specific policies and procedures.**

(1.) Indwelling venous/arterial blood-line:

Do not obtain blood from a heparinized access line, or indwelling heparin lock.

Note: The amount of blood required to adequately flush the line until it is free of contaminants is dependent on the amount of solution contained within the line. A typical line will require approximately 5.0 cc to clear the line. Greater volumes will be required to clear longer lines. **To ensure accurate results, the line must be clear of any residual fluid that might interfere with blood analysis and accurate test results.**

(a.) Wear gloves
(b.) Follow applicable department and Medical Center policies.
(c.) Discontinue fluids drip, if required.
(d.) Use a two-syringe technique, withdraw at least 5-10 ml and discard the first syringe.
(e.) **For P214 tubes:** Obtain 0.4cc of fresh whole blood with the second syringe for testing.

(2.) Venipuncture:

(a.) Wear gloves
(b.) Follow applicable department and Medical Center policies.
(c.) Prepare the venipuncture site by cleansing with alcohol and allow to dry completely.
(d.) **For P214 tubes:** Obtain 0.4cc of fresh whole blood for testing.

(3.) Extracorporeal blood line port:

(a.) Wear gloves
(b.) Follow applicable department and Medical Center policies.
(c.) It is recommended to flush the extracorporeal blood access line by withdrawing and discarding 5cc of blood.
(d.) **For P214 tubes:** Obtain 0.4cc of fresh whole blood with the second syringe for testing.

E. Specimen Rejection Criteria

Blood samples demonstrating any of the following conditions may interfere with the ACT assay.

1. Samples contaminated with heparin
2. Samples contaminated with tissue thromboplastin
3. Samples contaminated with indwelling intravenous solutions
4. Samples contaminated with alcohol cleansing solution
5. Samples with visible clotting or debris accumulation
6. Samples that are not tested **immediately** after collection

F. Sample Analysis--Test Procedure: Gloves should be worn

1. **To run an ACT using P214 ACT TUBES:**
   Used for ECMO
   Note: Gloves should be worn when collecting, handling, or testing blood specimens or handling the Hemochron Response analyzer.

a. **IMPORTANT***Prior to sample collection,** hold the ACT test tube vertically and tap the tube bottom several times on a horizontal surface to shake the activator particles into the test zone (bottom of the ACT tube).
b. **Prior to sample collection,** power ON the Hemochron analyzer. Press START 1 or 2 and verify that the system self-checks are OK. Troubleshoot if a self-check FAILS.
c. **Confirm that all required quality control checks have been performed and are acceptable on the analyzer and ACT tubes.**
d. **Samples should be analyzed immediately after collection at the patient's bedside or close proximity to the patient!!!**
e. **The analyzer should be located on a level surface, free of vibration or movement during the testing process.**
f. Flip open the cap of the plastic test tube and dispense exactly 0.4 ml of blood into the test tube. At the same time, depress the "START" button of the Hemochron test well as blood first appears in the tube.
g. Close the flip-top. Holding the test tube in an upright position with thumb and forefinger, mix blood and activator by gently flicking the bottom of the tube 5 to 7 times.
h. Insert test tube into the Hemochron test well and rotate the tube clockwise until the green "Detector" light is illuminated. Turn one additional revolution to assure that the green light remains on.
i. *****VERY IMPORTANT STEP FOR Hemochron Response***** ***Complete a. -h. above before entering PIN and patient ID.***
Users are required to enter a PIN ID (operator ID) and the correct patient ID (medical record number) using the numeric keypad. The analyzer is programmed to require these entries and the user will be prompted for the entry. Results will not display until the required information is entered. After entry of the required information, the Response will display the running time of the ACT from the time of tube insertion.
j. Once a clot has been detected, a beeping sound will be heard and the clotting time will flash on the display screen. **The ACT result will go away when the tube is removed from the test well. Results can be obtained from the patient database. See the Hemochron Response Operator Manual for details.**
k. **NOTE:** If there is an error, the error should be evaluated and the sample **recollected and re-tested**. The ACT tube cannot be remixed and used again. Results will not be accurate, since the blood will have already started the clotting process.

2. **All blood samples should be discarded in WFBMC-approved containers. Syringes and needles should be discarded in sharps containers. Follow applicable Medical Center policies.**

G. Result Reporting:

1. Record the ACT result on the department specific flow sheet. Patient identity should be verified throughout entire test process, from sample collection, to testing, to result reporting.
2. Results should be recorded with testing staff member's name, so that the testing personnel can be clearly identified.
3. Results should be clearly identified with the date and time the ACT was performed. Units of measure (seconds) should be reported with results. A clear audit trail should be established to determine testing personnel, reagents, and analyzer used for testing.
4. Each user site has site-specific guidelines for ACT therapeutic ranges.
5. Respond according to testing site department guidelines or per physician orders.
6. **Normal/Reference Range:**
   a. The expected response range for normal healthy volunteers is 110-182 seconds using p214 tubes.
7. **Verbal Critical Result and Order "Read Back"**
   All POCT sites should follow the WFBMC policy for "read back" of critical results and verbal orders. Anytime an order or critical result is verbally reported, "read back" should occur to ensure accuracy of results.

H. Clerical Errors:

If an error is discovered in identifying a patient sample or in reporting the results, the patient's physician should be notified immediately and repeat testing performed. Documentation on the site-specific patient care flow sheet should be clear as to the action that was taken.

I. Technical Limits/Critical Values:

1. **Unexpected results of >600 seconds should be properly evaluated for correct analyzer/tube performance and repeated with a freshly drawn sample to rule out sample contamination.** Verified results of > 600 seconds should be reported as >600 seconds on the patient's site-specific patient care flow sheet and the physician should be notified immediately.
2. **Results of 80 seconds or less may indicate improper instrument starting technique and should be repeated with a freshly drawn sample. Results less than 80 seconds are not considered valid.**
3. Any result that is not consistent with patient presentation should be followed-up with additional laboratory testing as deemed necessary by the physician.
4. When questionable results are obtained, proper instrument and tube performance should be verified by performing both levels of LIQUID AND ELECTRONIC quality control (QC) checks on each test well. ***Do not use the analyzer or tubes for patient testing if QC results are not within acceptable limits.*** Consider whether or not an appropriate uncontaminated sample was used for test analysis. e.g.: If the sample was collected from a line, consider whether or not the line was free and clear of any contaminant fluid that was previously flowing through the line.

J. Limitations of Procedure: (Results May Be Affected By...)

1. Incorrect sample volume added to tube.
2. Improper storage of test kits (exposure to prolonged heat or refrigeration) may affect results.
3. ACT's may be affected by hemodilution, cardiopledgic solutions, hypothermia, platelet dysfunction, hypo-fibrinogenemia and other coagulopathies and certain medications.
4. ACT's are affected by poor technique, including venipuncture and test procedure.
5. Inadequate specimen/reagent mixing may result in reduced precision and accuracy.

Test results which do not agree with expected values should be verified and evaluated by an alternative coagulation test.

K. Instrument Troubleshooting Notes:

1. **All instrument problems and troubleshooting actions should be documented on the ACT Daily Quality Control and Maintenance log in the problem log section.**
2. Before attempting repairs, perform a careful inspection of the instrument. A visual examination can frequently pinpoint the defect.
3. A complete list of fault codes, explanation and corrective actions can be found in the Troubleshooting section of the Hemochron Response Operator's Manual.
4. To help avoid stuck magnet errors, AFTER mixing the ACT tube, (blood with clot activator), try flicking the bottom of the tube immediately prior to inserting into the analyzer. This allows the magnet in the ACT tube to move from the plastic post in the ACT tube.
5. Review the Hemochron Response Operating Manual and applicable package inserts for questions regarding use of the Hemochron or special handling techniques.
6. Technical assistance is available from the manufacturer at 1-800-631-5945.
7. If the instrument problem cannot be resolved, contact the WFBMC Facility Services/Clinical Equipment Support (Bio-Med) for repair assistance.
8. The Point of Care Testing Coordinator may also be contacted for assistance.
9. Prior to patient use, follow instructions noted below whenever Hemochron analyzers are returned from repair (Bio-Med or manufacturer).

L. Response Analyzer Post-Repair Procedure

Whenever a Hemochron Response analyzer is returned from repair, at a minimum, the following items should be completed/verified prior to placing the analyzer back into patient use. Refer to the Hemochron Response Operator's Manual for detailed programming instructions.

1. Verify Date and Time programmed in the Hemochron analyzer
2. Set-up user PIN ID#'s in analyzer
3. Require PIN
4. Require electronic QC every 8 hours
5. Require patient ID entry
6. Set 911 attempts to 0 for each test well. Some sites may require exception to this rule, as necessary.
7. **SAVE ALL ENTERED INFORMATION IN THE ANALYZER. RE-VERIFY SETTINGS TO ENSURE THEY ARE CORRECT.**
8. Test both levels of Electronic QC in each test well and obtain acceptable results.
9. Test 2 levels of liquid QC in each test well and obtain acceptable results.
   a. Document results on the ACT Daily Quality Control and Maintenance Log and the ACT Liquid Quality Control Log.
   b. Records should indicate that QC was performed for post-analyzer repair.
10. Test a same-syringe patient comparison against another validated Hemochron Response analyzer. Document results on the ACT Analyzer Comparison Form.
11. A Hemochron Response Post-Repair Analyzer Checklist should be completed and forwarded to the Clinical Lab POCT Coordinator.

M. Calibration

Hemochron instruments do not require reagent calibration.

N. Maintenance—As applicable, all maintenance must be performed on BOTH test wells-- Maintenance checks may be required following repairs of the Hemochron or if instrument performance is in doubt.

1. **Monthly Maintenance**

   Check and clean, as necessary, the air-flow filter on the bottom of the Hemochron Response analyzer. Follow instructions in Hemochron Response Operator's Manual. This procedure is only application to analyzers that are equipped with the black plastic removable fan cover.

2. **Battery Care**
   a. Hemochron instruments can be operated either on the self-contained battery or plugged into the appropriate AC outlet.
   b. Routine charging and discharging of the nickel cadmium battery will improve its lifespan.
   c. When the batteries are drained to the point that valid testing cannot be performed , the instrument will display a BATTERY LOW message for the Response device. At this point, the instrument should be plugged in to an AC outlet for charging and operation.
   d. ACT tests can be performed on the Hemochron while it is charging.

3. **Visual Inspection/Cleaning-Performed after each patient use**

   Visual inspection should be performed after each patient use and cleaning of the test well and test tube drive collar of the Hemochron is to be performed as required for aesthetic purposes. The exterior of the analyzer should be disinfected between each patient use. Use WFBMC-approved disinfectant solution.
   a. Wearing gloves, clean any dried blood from the unit using a fresh 1:10 dilution of household bleach (sodium hypochlorite) with moistened cotton swabs.
      Note: The 1:10 bleach solution should be made daily to prevent loss of germicidal action during storage. It is also acceptable to use a WFBMC approved pre-packaged bleach wipe.
   b. Apply solution to clean and disinfect areas contaminated with residual dried blood.
   c. Solvents or strong cleaning solutions will damage and deform any plastic components of the instrument.
   d. Units that are unable to be cleaned should be placed in a clear bag with a biohazard label on the outside of the bag. The unit supervisor or Clinical Laboratory Point of Care Testing Coordinator should be notified, so appropriate action may be taken. Contaminated analyzers should be handled using Standard Precautions.
   e. **Any analyzer sent out of a department or patient care area should be disinfected prior to removal from the site.**

V. Quality Control

It is the responsibility of the staff member that performs patient ACT testing to ensure that required quality control checks have been performed on the analyzer and tubes prior to patient use. **(ALL QC results MUST be within acceptable limits prior to patient use)**

A. Daily QC for Hemochron Response-- Utilizing Electronic Quality Control (EQC) or Electronic System Verification Tube (ESVT)—also referenced as QC probe:

Electronic QC does **not** verify performance of the ACT tubes.

1. Two levels of ACT electronic quality control are performed each 8 hours of patient use on each test well.
2. The Hemochron Response utilizes a multi-level QC probe that contains 3 levels of QC on one probe. (100, 300, and 500 seconds)
3. As with routine patient ACT testing, Hemochron electronic controls are performed by insertion of the QC probes into the Hemochron test well.
4. ECMO utilizes the 100 and 300 second QC levels.
5. If the analyzer is not powered ON, turn on the Hemochron analyzer by pressing the START 1 or START 2 key pad. Self-tests will be displayed and should be OK. If a self-test fails, perform troubleshooting and document all actions on the QC/problem log.
6. Press the START button next to the desired test well and at the same time press the key pad next to the desired level of QC on the QC probe. The QC probe will sound for a few seconds. Insert the probe into the desired test well.
7. The red detector light by the selected QC level will illuminate, indicating test initiation.
8. When the QC device is inserted into the Response analyzer, the green detector light on the analyzer will illuminate.
9. The user is prompted for a PIN # (operator ID). Use the numeric key pad to enter the information. Press YES when entry is complete. The BACK SPACE key pad may be used to correct mistakes.
10. The analyzer will then prompt for the QC probe serial number. Use the numeric key pad to enter the information. Press YES when completed.
11. If the analyzer does not recognize the QC probe, press the appropriate MENU 1 or 2, select option 2 QC SELECTS and then option 3 ENTER ESV SN. After the information is entered, press the YES key pad.
12. When the QC probe reaches its' pre-programmed time, it will electronically simulate a test endpoint. The instrument will beep and display the test result.
13. If the instrument's detection system is functioning correctly, the time displayed should be within the acceptable limits noted on the ACT Daily Quality Control and Maintenance Log .
14. When the QC cycle is completed, remove the QC probe from the test well.
15. Normal and abnormal QC checks should be performed on each analyzer that is used for patient testing.
16. The QC results will no longer display once the QC probe is removed from the test well.
17. Results can be obtained from the analyzer's Quality Control data base. Refer to the Hemochron Response Operator's Manual for details.
18. If the incorrect QC level is selected on the QC probe, the appropriate level may be selected, prior to insertion of the QC probe into the analyzer. The QC probe will automatically cease the first test and initiate performance of the newly selected level of QC.

B. QC Documentation/QC Troubleshooting:

1. Upon completion of test analysis, record the QC values obtained on the ACT Daily Quality Control and Maintenance Log.
2. The acceptable ranges are listed on the daily QC log.
3. They are:
   a. **P214 Tube Users-ECMO**
      (1.) Normal—100 level: 90-110 seconds
      (2.) Abnormal—300 level: 290-310 seconds.
4. If the ACT values exceed acceptable range, repeat the **same** EQC level in the **same** test well.
5. If the EQC values are still unacceptable, try changing the batteries in the EQC probe and repeat QC testing.
6. If the problem does not resolve, try running both levels of liquid QC in each test well. If the liquid QC values are within acceptable limits, the Hemochron analyzer may be used for patient testing.
7. Suspect that the QC probe is faulty. Replacement of the QC probe may be necessary.

8. Contact WFBMC Facility Services/Clinical Equipment Support (Bio-Med) for assistance. Appropriate site-specific leadership should be notified. The Clinical Laboratory Point of Care Testing Coordinator should also be notified.
9. If either level of **liquid QC** is not within acceptable limits, the analyzer and tubes must be removed from service and sent to WFBMC Facility Services/Clinical Equipment Support (Bio-Med). Manufacturer technical support may be contacted at 1-800-631-5945.
10. **Patient results should NOT be reported from the ACT analyzer until QC problems are resolved and documented.**
11. **All QC failures and follow-up action should be documented on the ACT Daily Quality Control and Maintenance log in the problem log section. Documentation should be forwarded to the Clinical Lab POCT Coordinator each month.**
12. Each site is responsible for ensuring an adequate back-up plan in case of analyzer failure.
13. If any electronic QC procedure yields an on-screen ERROR message, or if the QC probe failed to yield acceptable results, discontinue use of the instrument for patient testing until the problem is resolved.
14. **Note: Regarding Battery Depletion**
    a. If a fault message is illuminated next to the test result, and/or the red lights on the QC probe are flashing, the batteries in the QC probe are nearly depleted and should be replaced.
    b. Refer to the appropriate electronic QC package insert for battery replacement instructions.
    c. The multi-level QC probe uses (2) AAA alkaline batteries.
15. **Not In Use Documentation**
    If the Hemochron ACT analyzer is not used on a particular day/8 hour shift for patient testing, it is acceptable to document "not in use" (NIU). All NIU documentation should be initialed by the staff member indicating the device was not used.

C. **Liquid Quality Control**

1. Two levels of liquid QC should be tested:
    a. Weekly--rotate among analyzers each week. Each analyzer should have liquid QC performed at least once each month.
    b. To verify correct performance of all types of ACT test tubes **prior** to placing the tubes into patient use--Each new box of ACT tubes should have 2 levels of liquid QC tested.
    c. If tube/analyzer performance is in doubt.

    Note: ALL QC results MUST be within acceptable limits prior to patient use.
2. **Liquid QC** is accomplished by using International Technidyne's Hemochron NORMAL(1) AND ABNORMAL(2) ACT HepCheck Whole Blood Control for p214 tubes.
3. The product is stable through the package expiration date when stored at 2-8°C. HepCheck QC vials may be stored at room temperature for up to 4 weeks. The expiration date should be modified when brought to room temperature. Do not expose to temperatures above 37°C or to temperatures below freezing. Refer to package inserts for additional information.

    Note: Gloves should be worn, when handling QC materials or performing testing.
4. **HepCheck Procedure for p214 Tubes**
    a. Level 1(catalog # DCP214-N) and 2 (catalog # DCP214-A) controls are provided separately.
    b. Remove the desired number of QC vials from the refrigerator and allow them to come to room temperature. (Could take up to 1 hour)
    c. **Reconstitution and testing of the QC material should be completed quickly. Once the dried material is reconstituted, the sample should be used immediately, as clotting will occur.**
    d. Visually inspect the vial to ensure the glass ampule is intact.
    e. Remove the label from the vial.
    f. **Insert the vial into the protective plastic sleeve.** Holding the vial upright, tap the vial on a table top to settle the glass ampule to the bottom of the vial.
    g. Crush the inner glass ampule by either bending the vial over the edge of a tabletop or by crushing the vial between two fingers. **Care should be taken to protect fingers from accidental exposure. Use the protective sleeve that is provided with the QC material.**
    h. Immediately repeat the crushing action 1-2 two additional times to ensure complete breakage of the ampule.
    i. Quickly invert the dropper vial end-to-end 10 times.

j. While inverting the vial (dropper tip down), use a downward snapping motion of the wrist to ensure the control material flows to the dropper tip.
k. Remove the vial cap.
l. Immediately dispense the entire contents of the QC material to fill the p214 tube to the fill line, or until all contents of the vial have been dispensed.

m. At the same time, depress the "START" button for the appropriate test well on the Hemochron as the QC material first appears in the tube.

n. Immediately, ensure that the top of the ACT tube is sealed, and holding the tube vertically, flick the bottom of the ACT tube 4-6 times to disperse the activator.

o. Insert the p214 tube into the appropriate test well and gently rotate the tube clockwise until the green 'detector' light remains lit.

p. **Response Users:** Will be required to enter a patient ID. Enter the numeric portion of the QC lot number as the patient ID.

q. The analyzer liquid QC menu may also be utilized. Refer to the Hemochron Response Operator's Manual for detailed instructions.

r. At the buzzer, record result. Quality control values are to be appropriately documented on the ACT Liquid Quality Control Log by the testing staff member. **All requested information should be documented. All QC values should be documented, including failed QC results. This allows tracking of on-going problems.**

5. **NOTE:** Acceptable liquid QC ranges can be found on the back of the package insert that comes in each box of QC. Use the correct range for your type of ACT tubes.
   a. **ECMO uses P214 tubes**.
   b. **QC ranges should be updated with each new lot of Quality Control reagent**.
6. If a QC result is outside of acceptable limits, circle the results and repeat the test in the same test well, using the same box of tubes.
   a. Should results persist outside the limits of acceptability, record all of the results obtained and pull the Hemochron tubes and analyzer from patient use, until the cause of the problem is identified.
   b. To troubleshoot failed quality control results, verify the following:
      (1.) Control material and tube expiration dates
      (2.) Instrument temperature
      (3.) Proper technique-Refer to QC specific package insert for troubleshooting tips.
      (4.) Sample volume used
      (5.) Presence of clots in the control material.
   c. If none of the above parameters are suspect, repeat the control process using control materials of the same lot number and test another box of tubes.
   d. If repeat QC testing does not fall within the expected range, obtain a tube from a different lot and repeat using the same lot of control material.
   e. If the control is still unacceptable, obtain a different lot of control material and repeat the test.
   f. If the repeat test is still outside of acceptable limits, **DO NOT use the tubes or Hemochron Response analyzer for patient testing until resolution is made. Notify the section supervisor/charge person and the Clinical Laboratory POCT Coordinator.**
7. All QC results should be documented on the ACT Liquid Quality Control Log along with action taken for out of control results. All requested information should be documented.
8. Troubleshooting actions should be documented on the ACT Daily Quality Control and Maintenance Log in the Problem Log section.

VI. Proficiency Testing:

Non-waived Point-of-Care Hemochron Response ACT Testing that is not considered our primary test method and is also covered by the same CLIA certificate as the Main Clinical Laboratory, CLIA ID 34D0664386, does not subscribe to a proficiency testing program. However, this ACT testing does participate in semi-annual comparison testing between site analyzers to verify performance of the ACT test method within the test site.

Sites not included on CLIA ID 34D0664386 must participate in a CMS-approved proficiency testing program.
Users should follow instructions provided with the survey samples. Current accrediting and regulatory standards are followed. The proficiency samples are rotated among different users. There is no communication between the Clinical Laboratory and POCT sites, regarding specific result values, until after the proficiency provider submission deadline. If proficiency survey sample results fail, the problem is investigated and resolved as necessary. Example, re-training, instrument performance evaluation or survey sample handling. Follow-up and corrective actions are documented.
Samples will be handled as follows:

i. All PT samples in the kit should be tested on the Same Day.
ii. One staff member should test All samples that come in the survey kit. (referenced as PT event)
iii. Testing of PT events should be rotated among testing personnel each calendar year, as available.
iv. 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 to make sure that one person is not always performing the PT.
v. One analyzer should be used to test All samples that come in a survey kit. (referenced as PT event)
vi. 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. The analyzer used for proficiency testing is not assigned. The analyzer used is at the discretion of the testing staff member, when this is the workflow for patient samples.

VII. Employee Certification/Training/Competency

Employee training documentation is completed upon training on the Hemochron Response ACT Test system. Each user of the Hemochron system should be trained prior to using the device for patient testing and should maintain updated competency records. New employees are reassessed at 6 months post-training and then annually, thereafter. After the first year of using the Hemochron device, competency is assessed annually. Current regulatory standards will be followed. Any user that fails to meet the competency requirements will need to be re-educated for use of the system. The Clinical Laboratory Point of Care Testing Coordinator and user site manager maintain training and competency records. The ACT Hemochron Response Competency Assessment Form should be used to document competency assessment.
Each testing staff member is assigned a specific user ID code (PIN), which serves as identification of testing personnel. User ID codes should not be shared among testing personnel. The Hemochron Response allows tracking of testing personnel. Patient and QC data base results are reviewed periodically.

VIII. Product Information

Manufacturer Technical Support: 1-800-631-5945

IX. Review/Revision/Implementation:

A. Review Cycle: Each 2 years

1. All new policies/procedures/guidelines and those that have major revision must be reviewed/signed by the CLIA Laboratory Medical Director.
2. Review/sign-off can be completed by the designated section Medical Director in the following circumstances:
    a. Biennial review
    b. Minor document revisions

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

X. Related Policies/Procedures/Guidelines:

A. PRO-POCT-LAB-18, Non-Waived Point of Care Testing (POCT) Quality Management Plan and Quality Control/Quality Assurance Procedures
B. Understanding of Responsibilities Between Testing Sites and the Clinical Laboratory for Point-of-Care Testing

XI. Attachments

None

XII. Other Associated Forms and Documents

- Hemochron Response Operator's Manual
- ACT Daily Quality Control and Maintenance Log
- ACT Liquid Quality Control Log
- ACT Hemochron Response Competency Assessment Form
- ACT Analyzer Comparison Form
- Hemochron Response Analyzer Post-Repair Checklist

XIII. Effective: 6/17/96

Revision Dates: 3/25/97
2/13/99
7/1/99
9/7/00
9/23/01
9/24/02
04/01/03
07/06
05/2011—policy numbering updated –change from NCBH to WFBMC
07/2016—policy numbering changed from PPB-WFBMC-LAB-775-10 to PRO-POCT-LAB-10

XIV. References:

A. HEMOCHRON Whole Blood Coagulation System Activated Clotting Time (ACT) Package Insert for FTCA510/HRFTCA510, P214 and FTK-ACT/HRFTK-ACT Tubes. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HM0459. 1213

B. HEMOCHRON Whole Blood Coagulation System Response Operator's Manual. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HR1574 10/04.

C. HEMOCHRON Whole Blood Coagulation System Electronic System Verification Tube Package Insert. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HR1114 10/03.

D. HEMOCHRON Whole Blood Coagulation System P214 Test Tubes HepCheck Whole Blood Control Package Insert. International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ, 08820. HL 1202 06/05.

Reviewed: _____ Date: 7/13/16

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