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Hemochron Signature Elite Activated Clotting Time (ACT)

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform Activated Clotting Time (ACT) testing with the Hemochron Signature Elite (Hemochron) instrument and to provide troubleshooting instructions for non-laboratory staff.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. The Hemochron instrument monitors the Activated Clotting Time (ACT) at the point of care (POC) for patients aged 18 years and above. This definitive result is used as an *in vitro* monitor for anticoagulant therapy during or post procedure and prior to arterial line removal. Whole blood is added to an activator (celite or silica and kaolin) and then timed for the formation of a clot.

B. The Hemochron utilizes a mechanical endpoint clotting mechanism in which clot testing occurs within the disposable ACT-LR or ACT+ cuvette. A whole blood sample is introduced and the system automatically moves precisely 15 µL of the sample to the test channel within the cuvette. The remainder of the sample, which is not needed, is automatically drawn into the waste channel of the cuvette. Sample-reagent mixing and test initiation are performed automatically with no operator interaction. Activation of timing begins immediately upon the

mixing of blood with the reagents. After mixing with the reagent, the sample is moved back and forth within the channel and monitored for clot formation. The clot formation mechanism consists of two LED optical detectors aligned with the test channel of the cuvette. The speed at which the sample moves between the two detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The Hemochron recognizes that the clot endpoint has been achieved when the movement decreases below a predetermined rate. The testing cycle is then terminated and the analyzer will display the coagulation time in seconds.

C. The ACT test is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The ACT-LR test demonstrates linear correlation to the anticoagulation effects of heparin up to 2.5 units/mL of blood. It is intended for use in monitoring low to moderate heparin doses frequently associated with procedures such as cardiac catheterization, Extra-Corporeal Membrane Oxygenation (ECMO), hemodialysis, and percutaneous transluminal coronary angioplasty. The ACT+ test is available for monitoring moderate to high levels of heparin (1-6 units/mL).

D. Overdosing heparin can result in bleeding, whereas, under-dosing heparin can lead to clotting. Therefore, monitoring heparin therapy is crucial in protecting against these adverse side effects.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when drawing and handling a blood specimen. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation
    1. No special patient preparation is needed.

B. Patient Identification
    1. Patients must be identified at the bedside using two identifiers (Joint Commission). Where applicable, scan the barcode on the patient's wristband to obtain the contact serial number (CSN).
    2. Areas where patients do not have wristbands or where the wristband is not readily accessible (e.g. Operating Room (OR), Cath. Lab, etc.) the patient CSN will be entered manually using the keypad. Verify that the identification (ID) number appears correctly on the display before proceeding with the ACT test.

C. Specimen Labeling
    1. ACT testing should be performed at the patient's bedside. If the specimen is taken to another location for patient testing, the specimen must be labeled with patient name and ID number (Joint Commission).

D. Specimen Types
    1. Whole blood from arterial or venous draw sites only.

E. Specimen Collection, Handling, Processing, and Disposal

1. Do not collect the specimen until the 5 minute count-down has begun on the instrument. See the Procedure section for more information. The cuvette must be quickly dosed with the specimen to prevent premature clotting in the syringe, which adversely affects the result.
    a. Note: If the collection and testing steps are performed by more than one person, communication throughout the process is essential to verify that the specimen is processed in a timely manner after specimen collection to obtain accurate results.
2. Verify that the specimen collection supplies are not expired.
3. All specimens for ACT must be free flowing venous or arterial blood. Do not use excessive force when expelling the blood specimen through the needle. This may lead to sample hemolysis.
4. A non-heparinized syringe must be used for specimen collection. A 23 gauge or larger needle should be used for blood collection.
5. Arterial or venous whole blood is obtained as follows:
    a. If the ACT is the only test ordered, use a two syringe collection process.
        i. Indwelling or Central Line: In the first syringe, draw 5 mL and discard into a biohazard container. In a second syringe (1 mL or 3 mL syringe) draw at least 0.2 mL.
        ii. Venipuncture: In the first syringe, draw 2 mL of blood and discard into a biohazard container. In a second syringe, (1 mL or 3 mL syringe), draw at least 0.2 mL.
        iii. Arterial Line: In the first syringe, draw 10 mL of blood and discard into a biohazard container. In a second syringe, (1 mL or 3 mL syringe), draw at least 0.2 mL.
    b. If other tests are ordered with the ACT, make sure that the ACT is drawn last and in a separate syringe.
6. Intravenous (IV) lines or Central Venous Access Device (CVAD) lines must never be used for ACT testing if heparin is being infused or used for flushing the line. Draw the ACT from another site.
7. Test the specimen immediately after collection.
    a. Specimens should not be preserved, transported, or referred to another area for testing as clotting begins as soon as the sample is collected. Delays in testing will yield falsely low results.
8. After testing the sample, dispose of the syringe in a biohazard container.
    a. Specimens should not be saved for later use or repeat testing.

F. Specimen Acceptability Criteria
1. Venous or arterial samples collected in a non-heparinized syringe tested immediately after collection.

G. Specimen Rejection Criteria
    1. Evidence of clotting
    2. Visible debris
    3. Incorrect sample types
    4. Incorrect collection devices
    5. Specimens must be free of contamination including:
        a. Tissue Thromboplastin
        b. Indwelling Intravenous Solutions
        c. Alcohol Cleansing Solutions
        d. Heparin
            i. Note: The waste syringe and specimen collection syringe cannot be subjected to a saline/heparin wash solution. The lines used for specimen collection cannot be contaminated with heparin.

IV. REAGENTS:

A. Hemochron Cuvettes (ACT-LR or ACT+)
    1. Availability: Each box contains 45 individually sealed cuvettes.
        a. Dearborn: The cuvettes are stored in the walk-in refrigerator in the Laboratory.
        b. Farmington Hills: Cath Lab orders and stores the cuvettes.
        c. Grosse Pointe: Cuvettes are obtained in the Laboratory in the Point of Care refrigerator located in Microbiology.
        d. Royal Oak: Cuvettes are stored in the Ancillary Testing workroom.
        e. Trenton: Cath Lab and Perfusion order and store the cuvettes.
        f. Troy: Cuvettes are stored in the Point of Care Store Room refrigerator.
        g. Wayne: Cath Lab and Perfusion order and store the cuvettes.
    2. Ingredients: Each cuvette is preloaded with a dried preparation of celite, stabilizers, and buffers.
    3. Handling: If stored in a refrigerator, allow the cuvettes to warm to room temperature for at least one hour before using for patient testing. Each box will be marked with the date placed at room temperature and subsequent room temperature expiration date. Cuvettes should never be exposed to temperatures exceeding 37 °C.
    4. Expiration: Unopened, pouched cuvettes are stable until the manufacturer's expiration date if stored in the refrigerator (2-8 °C). If a pouch is opened, but properly folded at the open end and refrigerated, the cuvette is stable for one day. Once removed from refrigeration, cuvettes should not be returned to a refrigerated state. If stored at room temperature (15-30 °C), the unopened cuvettes will expire 12 weeks after being removed from the refrigerator. After the pouch is opened, cuvettes are

stable for 8 hours at room temperature (stored in the folded pouch).

5. Warnings/Precautions: For *in vitro* diagnostic use only.

B. *direct*CHECK Level 1 (Normal) and Level 2 (Abnormal) Whole Blood Quality Control (QC) (ACT-LR and ACT+)

1. Availability: Each box contains 15 dropper vials of 0.5 mL dried whole blood control in a glass ampule provided with 0.7 mL of diluent. 15 reusable plastic protective sleeves are included to assist in the crushing of the glass ampules.
    a. Dearborn: The QC is stored in the walk-in refrigerator in the Laboratory.
    b. Farmington Hills: Cath Lab orders and stores the QC.
    c. Grosse Pointe: QC is obtained in the Laboratory in the Point of Care refrigerator located in Microbiology.
    d. Royal Oak: QC is stored in the Ancillary Testing workroom.
    e. Trenton: Cath Lab and Perfusion order and store the QC.
    f. Troy: QC is stored in the Point of Care Store Room refrigerator.
    g. Wayne: Cath Lab and Perfusion order and store the QC.
2. Ingredients: The controls consist of dried fixed bovine red blood cells, buffered sheep and horse plasma. The diluent consists of distilled water, sodium chloride, Tween 20, Proclin, anticoagulant, and calcium chloride.
3. Storage: Refrigerate vials at 2-8 °C (36-46 °F). Allow sufficient time for the vials to reach room temperature prior to testing (up to 60 minutes). Controls should never be exposed to temperatures exceeding 37 °C.
4. Expiration: Dry controls are stable until the manufacturer's expiration date when refrigerated. If stored at room temperature, the vials expire 4 weeks after removing from the refrigerator. Mark the vials with the new expiration date when removed from the refrigerator.
5. Handling: Reconstituted controls must be used immediately.
6. Precautions: For *in vitro* diagnostic use only. Discard the vials and used cuvettes in a biohazard container. Follow Standard Precautions/Hand Hygiene when handling any laboratory reagent or when performing testing. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used.

V. EQUIPMENT AND SUPPLIES:

A. Hemochron Instrument
B. Hemochron Power Cord
C. Gauze or Other Absorbent Material
D. Gloves
E. Specimen Collection Supplies (Including 1-3 mL Non-heparinized Syringe(s))

F. Protective Sleeve (for Liquid Quality Control)

G. Biohazard Receptacle

VI. CALIBRATION AND CALIBRATION VERIFICATION:

A. There is no calibration of the Hemochron as calibration is completed by the manufacturer.

B. Calibration verification is the process of assaying reference standards or calibration materials, in the same manner as patient samples, to confirm that the calibration of the analyzer has remained stable throughout the reportable range. Calibration verification is performed twice per year, approximately every 6 months. Two levels of whole blood quality control solution (Level 1-Normal and Level 2-Abnormal) are analyzed on each Hemochron used for testing.

1. Calibration Verification Procedure
    a. Obtain a batch of analyzers (up to 5 can be tested with each vial of QC).
    b. Run the directCHECK controls according to the Liquid Whole Blood Quality Control section.
    c. Acceptable ranges are found on the package insert of the control solution.
    d. Repeat the steps above until all analyzers have been tested.
    e. Maintain the results with the linearity/calibration verification documentation in the site-specific POC department.
2. Calibration Verification Failure Procedure
    a. If either of the controls falls outside of the acceptable ranges (one repeat allowed) on a particular instrument, that analyzer will be removed from service until corrective action is completed.

VII. MAINTENANCE:

The Hemochron is self-monitoring. It automatically monitors internal circuitry and reports problems on the display screen. Routine maintenance includes cleaning and recharging the battery.

A. Cleaning and Disinfection

1. Inspect and clean the cuvette opening, as needed. Remove residual dried blood and other foreign matter using water-moistened cotton swabs. Use a dry cotton swab to remove and residual water.
2. Clean and disinfect the instrument, if needed, with a hospital-approved disinfectant or bleach wipe. Be aware of the contact time of the wipe used. Do not spray directly on the instrument. Do not use solvents or strong cleaning solutions as they may damage the analyzer's plastic components.
3. Do not insert any foreign objects or cleaning agents into the cuvette opening.

B. Battery

1. A fully-charged lithium ion battery will operate the analyzer for at least two hours

continuously for 49 average test cycles. The “Battery is Low” message will appear on the display screen at the beginning of a test to alert the user if the battery is running low. The analyzer has approximately 10 minutes of running time from when this message first appears. If the message appears, use the supplied power cord to plug the analyzer into an alternating current (AC) wall outlet.

2. When the batteries are drained to the point that valid testing cannot be performed, the analyzer with display “Charge Battery”. The analyzer must be plugged into an AC outlet for operation and recharging. Testing can be performed immediately upon attaching the analyzer to a power supply.

C. Emergency Shut-Down

1. Press and hold the “Start” button for at least 4 seconds to shut down the Hemochron.
2. Unplug the Hemochron from the power source.

VIII. QUALITY CONTROL (QC):

A. Routine quality control testing of the Hemochron analyzer includes daily temperature verification (Self-Check) along with two levels of Electronic System Verification (EQC) measured every 8 hours that the analyzer is used for patient testing. Two levels of liquid whole blood quality controls are assayed to validate each shipment and/or lot of cuvettes in use and at least every 30 days to meet the Individualized Quality Control Plan (IQCP) requirements. The liquid whole blood quality controls are also used to evaluate new Hemochron analyzers, validate Hemochrons with reported problems, and to verify each instrument’s calibration approximately every 6 months.

1. Note: Some of the instrument prompts may not appear based on the site-specific instrument configuration.

B. Self-Check

1. The instrument performs a self-check every time a test is initiated by inserting a cuvette. An error message will display and testing is prohibited if the following checks fail:
    a. Adequate battery power to complete a full test
    b. Pumps and sample-sensing Liquid Electronic Diodes (LED) are functioning properly
    c. Cuvette temperature is warmed to 37 °C $\pm$ 1.0 °C
    d. Sample is present and is of sufficient size to perform the assay. This checks that the pumps and sample sensing LEDs are functioning properly and that the cuvette is adequately sealed.
    e. Internal timers function correctly for each test. If the system timer and assay timer disagree, a real-time clock error message will be displayed and the test result will not be reported.

C. Electronic Quality Control (EQC)

1. EQC simulates test initiation and clot detection in the same manner as patient assays are performed.
2. The Hemochron is in a constant awake mode, if attached to a power supply and is turned on, and will automatically perform EQC every 8 hours. This may take up to 10 minutes to complete. To repeat a failed EQC run, or to initiate EQC before a scheduled time, follow the steps below:
    a. Press the “QC” button. It will display the amount of time remaining before EQC is due and provides the option to run EQC.
    b. Press the “1” button. The display will read “EQC” in the upper left corner and “TEMP:_____” as it begins warming. Once the test chamber reaches 37 °C, “QC Normal” displays as the instrument counts from 0 to 30. “QC Abnormal” displays as it continues counting up to 300 or 500, depending on the cuvette type(s) used on the instrument. “Test in Progress” remains on the display until EQC is finished.
    c. Results are displayed on the screen and are written to the QC database. Note: If one parameter fails, the test will stop and record all results as failed. If the user aborts the EQC, it is not saved to the database and patient testing will not be allowed.
    d. EQC Acceptable Ranges
        i. Normal Level: 29-31 seconds
        ii. Abnormal Level: 299-301 (instruments configured for ACT-LR only)
        iii. Abnormal Level: 499-501 seconds (instruments configured for ACT-LR and ACT+)

D. 911 Option
1. This option is available for a STAT test only. EQC may be bypassed once to allow patient testing.
    a. Press “Cancel” to stop EQC. The analyzer display will inquire:
        - Abort Test?
        - Sure? 1-YES 2-NO
    b. Press the "1" button.
    c. The display will prompt:
        - Run EQC
        - Check QC-Status
        - Insert..... .....Cuvette
    d. Insert a cuvette for patient testing.
    e. A beep is heard and “EQC Expired” will flash briefly before this message appears:
        - 1-QC Normal

- 2-QC Abnormal
- 3-Patient Result

f. Press the “3” button. If option 3 does not appear, there are no more 911 Options remaining and EQC must be performed before patient testing.

g. The display inquires:
   - 1 911' ;s LEFT
   - USE 911 1-YES 2-NO

h. Press the “1” button.

i. Proceed with patient testing as outlined in the Procedure section.

j. When the patient test is complete, remove the cuvette and immediately perform EQC by pressing the “QC” button then “1” to avoid instrument lock-out.

E. Liquid Whole Blood Quality Control

1. Remove normal and abnormal liquid whole blood quality control vials and respective testing cuvettes from the refrigerator and allow them to warm to room temperature 15-30 °C (59-86 °F). This can take up to 60 minutes.
2. Confirm that the QC and cuvettes are not expired.
3. Visually inspect the QC vials to confirm that the glass ampules are intact.
4. Insert a cuvette into the slot on the side of the analyzer.
5. After the cuvette is inserted, “Cuvette LOT” will display. Press the “PRINT/SCAN” button to scan the barcode from the cuvette pouch. “Lot Stored” will appear on the display.
6. At the “Enter OID” prompt, position the scanner window 2 to 4 inches from the operator ID barcode and press “PRINT/SCAN”. The operator ID and a “Stored” confirmation message will appear. If an unacceptable operator ID is entered, “ID is Not Valid” will display.
7. Press the “QC” button to display the “QC SELECTS” menu. Note: A cuvette must be inserted into the analyzer to display the "QC SELECTS" menu.
8. Select “1” before testing the normal control and “2” for the abnormal control. Once the QC type is selected, it cannot be changed. Make sure to test the control level that was selected.
9. Press the “PRINT/SCAN” button to scan the barcode from the QC package insert. Verify that the QC package insert scanned corresponds with the correct lot number of control material.
10. During the pre-warm stage, observe the display for fault/warning messages. The following prompts are briefly displayed:
    - Priming Pump.....
    - ...Warming.....

11. The analyzer beeps once when read and the screen alternately displays:
    - Add Sample.....
    - .....Press Start
    - and a 5 minute count down.
12. The instrument will remain in this mode for 5 minutes before a “START Timed Out” error occurs. This will require the removal of the cuvette and its reinsertion in order to continue with QC testing.
13. Reconstitute the room temperature QC dropper vial as follows:
    a. Remove the label from the vial
    b. Insert the vial into a protective sleeve.
    c. Holding the vial upright, tap the vial on a tabletop to settle the glass ampule to the bottom of the vial.
    d. Crush the inner glass ampule by using the enclosed ampule crusher device provided in each box. Immediately repeat the crushing action 2 additional times to guarantee complete breakage of the glass ampule.
    e. Invert the dropper vial quickly end to end 10 times.
    f. While inverting the dropper vial (tip down), use a downward snapping motion of the wrist so the control material flows to the dropper tip and bubbles float to the top.
    g. Remove and retain the vial cap.
    h. Squeeze the vial and discard the first drop of the control material into the vial cap or gauze. If mixing was done properly, the drop should appear red.
14. Quickly dispense as many drops of control as needed to fill the inner cuvette well flush to the top. Should a large dome of blood extend over the top of the sample well, push the excess blood into the outer overflow well. Press the “START” key immediately. Repeat with up to 5 analyzers.
15. The display may indicate fault conditions and testing will be terminated if a sampling error (Sample Too Large, Sample Too Small, or Sample Not Seen) is detected. Refer to the Troubleshooting section for more information.
16. The elapsed time is displayed with the message “Test in Progress” until the test is completed.
17. A single beep signals the end of the test and the final results are calculated and displayed. Results are saved in the database with the date, time, operator ID, and error message (if a fault is detected).
18. Remove the control vial from the protective sleeve and discard the vial, cap, and cuvette in a biohazard container.
19. Repeat these steps for the other liquid whole blood QC level.
20. Acceptable ranges are found on the package insert. If QC fails, follow procedure outlined below. QC must pass before patient testing can continue.

F. New Lot Validation for Cuvettes and Liquid Quality Controls

1. Each new lot or shipment of Hemochron cuvettes will be validated in conjunction with a cuvette lot which is currently in use. Each new lot of liquid whole blood QC will be run to verify the manufacturer's range before use.
    a. Cuvette Validation
        i. Obtain 2 cuvettes from different boxes, if applicable, for each lot number to be validated. Allow them to reach room temperature.
        ii. Remove one vial of each level (Normal and Abnormal) QC material from the refrigerator and allow to reach room temperature.
        iii. Follow the steps for testing in the Liquid Whole Blood Quality Control section.
    b. Liquid QC Validation
        i. Remove 3 vials of each level of QC material, to be validated, from the refrigerator allow them to reach room temperature.
        ii. Obtain the appropriate number of cuvettes to perform testing.
        iii. Follow the steps for reconstituting the vials and testing liquid QC as described in the Liquid Whole Blood Quality Control section.
2. Document the results on the Hemochron New Lot Number QC Form. See the attachment.
3. Verify that all results pass. Cuvettes and QC may not be used for patient testing until all results are acceptable.

G. Quality Control Failure Procedure

1. If results are outside of the acceptable range, the following items should be verified:
    a. Verify the QC and cuvettes are not past their expiration dates.
    b. Confirm proper temperature storage for QC and cuvettes.
    c. Verify that the instrument passed EQC and Self-Check.
    d. Confirm the proper procedure and technique were followed.
    e. Follow the Corrective Action recommendations in the chart below.
2. If none of the above parameters are suspect, repeat the test using new QC and cuvette.
3. If the repeat does not fall within the expected range, follow the site-specific instructions below for assistance:
    a. Dearborn: Call Perfusion at 947-522-9766 or 313-593-5988 or call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
    b. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167.
    c. Grosse Pointe: Call POC at 313-473-1831 or the Laboratory at 313-473-1637.

d. Royal Oak: Call Ancillary Testing at 248-898-8012.

e. Trenton: Call Perfusion at 313-996-7479 or the Trenton Lab Manager at 734-671-3859.

f. Troy: Call Decentralized Testing at 248-964-8009.

g. Wayne: Call Perfusion at 313-996-7479 or the Wayne Lab Manager at 734-467-4233.

Problem	Cause	Corrective Action
QC Value Below Published Range	Reconstituted control was not thoroughly mixed. Time period between control material mixing and addition to test cuvette was too long.	Repeat test, making sure the inner glass ampule is crushed at least 3 times and reconstituted control is thoroughly mixed by inverting end to end 10 times. Immediately discard the first drop and dispense QC material into cuvette and start the analysis.
QC Value is Above Published Range	Inner glass ampule was not adequately crushed. Reconstituted control was not thoroughly mixed. Vial cap was removed prior to inverting and diluent leaked from vial.	Repeat test verifying that the inner glass ampule is crushed at least 3 times prior to mixing. Mix by inverting the vial end to end 10 times. Make sure the vial cap is not removed prior to mixing.
Fault Message Obtained (See Troubleshooting Section)	Reconstituted control was not thoroughly mixed. Bubbles are present in QC when added to cuvette.	Repeat test verifying that inner glass ampule is crushed at least 3 times and QC was mixed well by inverting end to end 10 times. Avoid excessively vigorous shaking that may lead to the formation of bubbles. Use a downward snapping motion of the wrist prior to dispensing the QC into the cuvette sample well.

IX. INSTRUMENT COMPARISONS:

A. Instrument comparisons, using both patient samples and liquid QC materials, are performed to verify the agreement between analyzers is within 10% and acceptable performance is demonstrated at various ranges for each cuvette type in use for a particular analyzer.

B. Instrument comparisons are performed twice per year (approximately every 6 months) on all the Hemochron analyzers for each cartridge type in use. See the Point of Care Testing Policy.

C. Because there is no lab analyzer to compare to the Hemochron for ACT results, one Hemochron is designated as the reference and the other Hemochron(s) are compared to the reference analyzer.

1. Take up to 5 Hemochron instruments to a location that is actively performing testing. A random patient sample is selected to be run on each of the analyzers. It is

preferable to have one sample drawn before heparin is administered as well as another collected after heparin administration. This will be done for each cuvette type in use.

a. Note: One set of comparisons is performed using patient samples. The second set may be performed using QC material.

2. Prepare the Hemochrons for running a patient ACT test. See the Procedure section.
3. Scan a training barcode or use a dummy number (i.e. 111111111) for the patient ID.
4. Document the results on the Hemochron Instrument Comparison form. The site POC Manager, Supervisor, or designee will review the comparison results before submitting to the Technical or Medical Director for review.
5. Troubleshoot and resolve any failures and document issues on the Hemochron Instrument Comparison form before releasing the instrument for patient testing.
6. If a comparison fails twice on the same instrument:
    a. Send the instrument to the site-specific BioMed Department for cleaning.
    b. Upon return from BioMed, repeat the comparison study.
    c. If the comparison fails, again, perform comparisons using 5 of each cuvette type that is validated on the instrument in question. If 2 or more of the 5 comparisons (per cuvette type) fails, the instrument must be removed from use. Contact the manufacturer for further instructions. The Technical and/or Medical Director may also review on a case-by-case basis.

X. PROCEDURE:

Note: Some of the instrument prompts below may not appear based on the site-specific instrument configuration.

A. The instrument should be set-up and ready for sample application (i.e. the 5 minute count-down must be in progress) before collecting a patient sample.
B. Open one cuvette pouch just prior to patient testing. Cuvettes must be at room temperature and not expired.
    1. Note: If performing multiple ACT tests throughout a case, the same cuvette type should be utilized to maintain consistency in resulting and dosing.
C. The analyzer prompts the operator to “Insert…… ……Cuvette”. Insert the cuvette into the right side of the instrument with the blood reservoir facing up.
    1. Note: Do not force the cuvette. Remove the cuvette and reinsert it if resistance is met.
D. After the cuvette is inserted, “Cuvette LOT” will display.
E. Press the “PRINT/SCAN” button to scan the barcode from the cuvette pouch. The “Lot Stored” message will appear on the display.
F. "Enter OID" will display. Press the “PRINT/SCAN” button to scan the operator ID from the

barcode on the badge. “Stored” will appear on the display if the operator is valid or “ID is not Valid” is displayed followed by the OID prompt if an unacceptable operator ID is entered.

G. "Enter PID" will display next. Press the “PRINT/SCAN” key to scan the patient ID from the wristband (preferred method) or manually enter the patient ID using the keypad, then press and hold the “ENTER” key. “Stored” will appear on the display.

H. The analyzer will automatically identify the test cuvette and display the test type in the upper right hand corner. While the cuvette is warming up (can take up to 60 seconds) and the analyzer is performing the Self-Check, the display will briefly read “Priming Pump…… ….Warming……”. Observe the display for fault messages and refer to the Troubleshooting section, if necessary, for instructions.

I. When the Self-Check cycle is completed, the analyzer beeps once and alternately displays “Add Sample…… ……Press Start”.

    1. Note: The analyzer will remain in this ready mode for 5 minutes before a “START Timed Out” message will appear. The same cuvette may be reinserted once more to begin a new pre-warm cycle.

J. Collect the sample according to the Specimen Collection and Handling section.

K. Working quickly, waste one drop of sample on an absorbent surface, then dispense the sample into the center sample well of the test cuvette, filling from the bottom up. If the meniscus of the blood sample extends above the top of the well, push the excess blood into the outer overflow area of the sample well.

L. Press the “START” key. A single beep will signal the start of the test.

    1. Note: The analyzer displays an error message if an incorrect sample has been provided. Restart the test with a new cuvette. Samples with hematocrits less than 20% or greater than 55% are not recommended due to an optical density outside the level of detection on this analyzer. This may issue the error “Sample Not Seen”.

M. Test completion (clot detection) will be indicated by a single beep. Final results are calculated and displayed on the screen.

N. For interfaced instruments, if, for any reason, the operator does not want the result to transmit to the patient’s chart (questionable result, poor technique, diluted sample, etc.) the “NOTE” key on the Hemochron must be pressed (while the result is still visible on the display). Choose the “1” comment “DO NOT UPLOAD” to prevent that result from transmitting to the patient’s electronic health record (EHR). Press “CANCEL” to exit.

    1. Note: Once the cuvette is removed from the analyzer, the result will vanish from the display but may be retrieved from the database (see the Result Review section) or, if the download has occurred, from the patient’s EHR.

O. Allow the test to go to completion. Removing the cuvette before the test has reached its end-point will not give any result in the patient’s electronic health record.

P. Remove the cuvette and discard in a biohazard container.

XI. RESULT REPORTING:

A. Upon test completion, report all test results to the clinician who ordered the ACT test.

1. Dearborn: Plug the patch cable into the Ethernet port. Press the “DATA BASE” button then “6 – POCT>>NET” to download results into the patient’s EHR.
2. Farmington Hills: Plug the patch cable into the Ethernet port. Press the “DATA BASE” button then “6 – POCT>>NET” to download results into the patient’s EHR.
3. Grosse Pointe: Plug the patch cable into the Ethernet port. Press the “DATA BASE” button then “6 – ITC>>NET” to download results into the patient’s EHR.
4. Royal Oak: Plug the patch cable into the Ethernet port. Press the “DATA BASE” button then “6 – POCT>>NET” to download results into the patient’s EHR.
5. Trenton: Record the result in the Epic procedure log.
6. Troy: Plug the patch cable into the Ethernet port. Press the “DATA BASE” button then “6 – POCT>>NET” to download results into the patient’s EHR.
7. Wayne: Record the result in the Epic procedure log.

XII. EXPECTED VALUES AND INTERPRETATION OF RESULTS:

Normal Ranges

A. ACT-LR: 125-175 seconds
B. ACT+: 108-141 seconds

Target Values

A. Farmington Hills
    1. ACT-LR: <150 seconds for baseline
    2. ACT-LR: <170 seconds for sheath pull
    3. Target ACT values must be greater than 250-300 seconds to accomplish therapeutic levels of anticoagulation.

B. Grosse Pointe
    1. ACT-LR: <150 seconds for baseline
    2. ACT-LR: 200-300 seconds (or twice the baseline) for therapeutic vascular surgery
    3. ACT-LR: <170 seconds for sheath pull
    4. Target ACT values must be greater than 250-300 seconds to accomplish therapeutic levels of anticoagulation.

C. Royal Oak
    1. ACT-LR: >250 seconds for interventions (procedure dependent)
    2. ACT-LR: <190 seconds for sheath line removals
    3. ACT+: >410 seconds post-heparin dose for open heart cases

D. Trenton

1. <170 seconds for sheath line removal

E. Troy

1. ACT-LR: 70-120 seconds for baseline
2. ACT-LR: 190-220 seconds for therapeutic anticoagulation
3. ACT-LR: >250 seconds for vascular intervention, or per vascular surgeon
4. ACT+: >450 seconds for cardiopulmonary bypass, or per cardiac surgeon

XIII. REPORTABLE RANGE:

A. ACT-LR 65-400 seconds

1. Results less than 65 will read “Out of Range – Lo” and will transmit to the Laboratory Information System (LIS) as “<65 sec.”. A <65 result will be trapped in the Telcor QML software and will require POC staff to review the result.
2. Results above 400 will read “Out of Range – Hi” and will transmit to the LIS as “>400 sec.”.

B. ACT+ 68-1005 seconds

1. Results less than 68 will read “Out of Range – Lo” and will transmit to the LIS as “<68 sec.”.
2. Results above 1005 will read “Out of Range – Hi” and will transmit to the LIS as “>1005 sec.”.

XIV. CRITICAL VALUES:

None

XV. RESULT REVIEW:

A. Press "DATABASE" to display the database menu.

B. Press "4-Display Pat". The first page of the results for the most current test record is displayed.

C. Press "9" to display additional pages of the record.

D. To scroll through additional test records, press "ENTER" to see the next record or "0" to see the previous record.

XVI. SYSTEM DOWNTIME:

A. If the Hemochron does not download results, continue to enter the operator and patient ID and proceed with testing. When the system becomes available, follow the steps in the Result Reporting section to download patient results.

XVII. LIMITATIONS AND INTERFERING SUBSTANCES:

A. The Hemochron instruments are designed for use only with Hemochron test cuvettes.

B. Test cuvettes and QC must be properly stored according to the instructions in the package insert and in this procedure. Expired testing cuvettes and QC should not be used.

C. The Hemochron is intended for use in monitoring patients receiving heparin anticoagulation therapy who attain a blood heparin concentration of more than 1 but less than 6 units of heparin per mL of blood.

D. Samples with hematocrits less than 20% or greater than 55% may exhibit an optical density outside the level of detection on the Hemochron. In such cases, a “Sample Not Seen” error message will be displayed.

E. The celite ACT equivalent clotting times expressed for the ACT+ are based on the results of correlation studies. Linear regression models measure similarity of test results between different methods but do not assure identity. Thus, for any similarly conducted side-by-side comparison of the ACT+ and ACT-LR, actual differences of clotting time may be observed. When performing multiple ACT tests in a short period, the same cuvette type must be used for the duration of the procedure.

F. The Hemochron is not intended for use for patients on Aprotinin, a protease inhibitor. Results will be artificially prolonged.

G. The effects of agents such as aspirin, tranexamic acid, DDAVP, anti-fibrinolytics, defibrinating agents (e.g. Ancrod), direct thrombin inhibitors (e.g. hirudin), and platelet preserving agents such as GPIIb/IIIa inhibitors (e.g. ReoPro®) are not established.

H. As with all diagnostic tests, Hemochron results should be scrutinized in light of the patient’s condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient’s clinical status should be repeated or supplemented with additional test data.

I. Do not expose the Hemochron instrument to extremes in temperature (below 15 °C or above 37 °C).

XVIII. TROUBLESHOOTING:

A. Hemochron test results are affected by poor technique during blood collection and delivery to the sample well. The accuracy of the test is largely dependent upon the quality of the sample collection and the transfer of the blood to the test cuvette. Tests may be affected by any of the following conditions:

1. Poor blood collection technique
2. Failure to discard an adequate amount of blood before collecting the sample
3. Drawing blood from heparin infused lines or lines flushed with heparin
4. Foaming of the sample (air bubbles)
5. Hemolysis
6. Delays in dispensing specimen to the test cuvette and/or initiating the start of the

test

7. Clotted or partially clotted blood
8. Unsuspected anticoagulation with either heparin or warfarin
9. Hemodilution, cardioplegic solutions, hypothermia, platelet dysfunction, hypofibrinogenemia, other coagulopathies, and certain medications
10. Presence of lupus anticoagulant
11. The quality of the blood specimen may be affected by unsuspected anticoagulation such as indirect factor Xa inhibitors (enoxaparin, fondaparinux, direct factor IIa inhibitors (argatroban, dabigatran), and direct factor Xa inhibitors (apixaban, rivaroxaban))
12. Poor test procedure technique

B. Appropriate action should be taken when a problem arises with the Hemochron. Use the following chart to aid in troubleshooting.

Error Message	Cause	Corrective Action
CHARGE BATTERY	Battery is depleted below predetermined level	Plug instrument to AC outlet to charge battery.
BATTERY FAULT	Battery is discharged	Charge battery for 16 hours.
EXTERNAL TOO HIGH	AC power plug voltage exceeds 12.7 v	Disconnect from AC outlet and contact the POC department.
BATTERY TOO HIGH	Battery voltage exceeds 8.8 v	Disconnect from AC outlet and contact the POC department.
MEMORY FAULT	Malfunction in computer's memory	Contact the POC department.
RTC.....FAULT	Cannot communicate with external Real Time Clock	Contact the POC department.
RTC	Real Time Clock	Contact the POC department.
Cuvette Removed	Cuvette was prematurely removed from instrument while testing was in progress	Repeat test with new cuvette.
Detector Fault	Light path between LED and detectors is blocked	Repeat test with new cuvette.
Heater Too Cool	Incubator remained below 36 °C after 90 seconds	Charge battery.
Heater Too Hot	Incubator exceeded 38 °C for 2.5 seconds	Repeat test with new cuvette.
Out of Range - Lo	Test result is outside whole blood clinical ranges. Sample has clotted prematurely, or did not mix correctly in	Repeat test with new cuvette.

	cuvette. Bubbles may be present.	
Out of Range - Hi	Test result is outside whole blood clinical range.	The system will automatically download the result to the patient's EHR. However, if the result is not compatible with the clinical picture, choose "DO NOT UPLOAD" on the Hemochron and repeat the test.
Premature Sample	Sample was detected at front detector before specified time period. May occur if sample is added before pump-priming sequence is complete.	Repeat test with new cuvette.
Sample Not Seen	Sample has not reached front detector in specified time period.	Repeat test with new cuvette. If error persists, check the hematocrit.
Sample Too Large/ Sample Too Small	Excess or insufficient sample.	Repeat test with new cuvette.
Sample Pos Fault	Sample has moved outside of testing area in cuvette.	Contact POC department.
START Timed Out	Start button was not pressed within 5 minutes after entering ready mode.	Remove cuvette and reinsert cuvette, again.
User Abort	The test was aborted by the user.	Repeat test.

If the problem cannot be resolved using the chart above, contact the site-specific POC department. A loaner instrument may be available for use.

A. Dearborn: Call Perfusion at 947-522-9766 or 313-593-5988 or call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
B. Farmington Hills: Call the POC/Quality Lead MT at 947-521-7167.
C. Grosse Pointe: Call POC at 313-473-1831 or the Laboratory at 313-473-1637.
D. Royal Oak: Call Ancillary Testing at 248-898-8012.
E. Trenton: Call Perfusion at 313-996-7479 or the Trenton Lab Manager at 734-671-3859.
F. Troy: Call Decentralized Testing at 248-964-8009.
G. Wayne: Call Perfusion at 313-996-7479 or the Wayne Lab Manager at 734-467-4233.

XIX. REFERENCES:

A. Hemochron Whole Blood Microcoagulation System Operator's Manual, Accriva Diagnostics, Inc., 6260 Sequence Drive, San Diego, CA 92121, revision HX1101EN 03 2019 class="underline wym_style">www.accriva.com
B. Hemochron Whole Blood Microcoagulation Systems ACT-LR Package Insert, Accriva Diagnostics, Inc., 6260 Sequence Drive, San Diego, CA 92121, revision FB5936WEU 01 2017

class="underline wym_style">www.accriva.com >

C. Hemochron Whole Blood Microcoagulation Systems ACT+ Package Insert, Accriva Diagnostics, Inc., 6260 Sequence Drive, San Diego, CA 92121, revision FB5935WEU 01 2018 class="underline wym_style">www.accriva.com >

D. directCHECK Whole Blood Control Package Insert, Accriva Diagnostics, Inc., 6260 Sequence Drive, San Diego, CA 92121, revision HL1235 03/2006 class="underline wym_style">www.accriva.com

E. Point of Care Testing Approval Process

F. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

G. CLSI H21 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-based Coagulation Assays and Molecular Hemostasis Assays, 5th Edition 1/23/2008, Clinical and Laboratory Standards Institute, 950 W Valley Rd Suite 2500, Wayne, PA 19087, clsi.org

Attachments

Hemochron Instrument Comparison.pdf

Hemochron New Lot Number Validation.pdf

Hemochron Training and Competency Assessment.pdf

Hemochron Training Guide.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Muhammad Arshad: Physician	3/1/2023
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	3/1/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	2/14/2023
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	2/10/2023
CLIA Medical Directors	John Pui: Chief, Pathology	2/10/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	2/10/2023

Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	2/10/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	2/9/2023
	Caitlin Schein: Staff Physician	1/26/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	1/9/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	1/6/2023
	Jessica Czinder: Mgr, Division Laboratory	1/6/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Trenton, Troy, Wayne