**Point of Care Activated Clotting Time Testing: Hemochron Signature Elite**

**Procedure**

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**DESCRIPTION/OVERVIEW**

1. **PURPOSE**
   1.1. The Hemochron Activated Clotting Time (ACT) is a quantitative assay for monitoring heparin anticoagulation during various medical procedures.
   1.2. The HEMOCHRON Jr. Low Range Activated Clotting Time (ACT-LR) cuvette assay demonstrates a linear response to the anticoagulation effects of heparin at doses up to 2.5 units/cc of blood. It is intended for use in monitoring low to moderate heparin doses frequently associated with procedures such as cardiac catheterization, Extracorporeal Membrane Oxygenation (ECMO), hemodialysis, and Percutaneous Transluminal Coronary Angioplasty (PTCA). This test is affected by aprotinin.
   1.3. The HEMOCHRON Jr. ACT+ cuvette assay demonstrates linear correlation to the anticoagulation effects of heparin between 1.0 and 6.0 units/cc of blood. It is intended for use in monitoring moderate to high heparin doses frequently associated with angioplasty and cardiopulmonary bypass surgery. The ACT+ is not sensitive to very low levels of heparin such as those encountered in critical care. The test is unaffected by aprotinin.

2. **PRINCIPLE**
   2.1. The HEMOCHRON Microcoagulation Systems utilize a mechanical endpoint clotting mechanism in which testing occurs within the disposable cuvette. Following whole blood sample introduction, the instrument precisely measures 15 microliters of blood and automatically moves it into the test channel within the cuvette. The remainder of the blood sample, not needed for testing, is automatically drawn into the waste channel of the cuvette. Sample/reagent mixing and test initiation are performed automatically, requiring no operator interaction. After mixing with the reagent, the sample is moved back and forth within the test channel and monitored by the analyzer for clot formation. The clot detection mechanism consists of two LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves between the two detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The instrument recognizes that a clot endpoint has been achieved when the movement decreases below a predetermined rate. Electronic optical detection of a fibrin clot in the blood sample automatically terminates the test. The instrument’s digital timer displays the Celite® equivalent ACT value in seconds in order to provide a familiar clinical format and thus facilitate accurate clinical test result interpretation.

**REFERENCES**

4. directCHECK® Whole Blood Control ACT+, Level 1 and Level 2 Package Inserts, latest edition.
5. directCHECK® Whole Blood Control ACT-LR, Level 1 and Level 2 Package Inserts, latest edition.

AREAS OF RESPONSIBILITY
1. POCT ACT testing can be done on any patient at University Hospital on receipt of an order from a physician or nursing staff designate.
2. Staff who have satisfied initial and ongoing competency requirements may perform the testing.

PROCEDURE
1. EQUIPMENT
   1.1. HEMOCHRON Signature Elite Microcoagulation Instrument
   1.1.1. 12 volt Transformer
2. REAGENTS
   2.1. HEMOCHRON Jr. ACT+ test cuvette.
   2.2. HEMOCHRON Jr. ACT-LR test cuvette.
   2.3. directCHECK® Whole Blood Control ACT+, Level 1 and Level 2.
   2.4. directCHECK® Whole Blood Control ACT-LR, Level 1 and Level 2.
3. ORDERING INFORMATION
   3.1. All equipment and reagents are purchased through International Technidyne Corporation.
   3.2. Reagent orders are coordinated through the UH POCT office for lot number sequestering. Please contact the UH POCT office at 2-0980 for assistance.
4. STORAGE
   4.1. Test Cuvettes
       4.1.1. When refrigerated (2-8°C), the foil-pouched test cuvette is stable until the manufacturer’s expiration date.
       4.1.2. Room temperature storage (15-30°C) is optional for sealed-pouched cuvettes. Re-dating is necessary if stored at room temperature. The cuvettes are good for a maximum of twelve weeks at room temperature, but must never exceed the manufacturer’s expiration date.
       4.1.3. Once a pouch is opened, the cuvette (stored in the folded pouch) is stable for only one day under refrigerated (2-8°C) conditions.
       4.1.4. HEMOCHRON Jr. cuvettes should not be exposed to temperatures in excess of 37°C.
   4.2. Liquid Quality control
       4.2.1. When refrigerated (2-8°C), the vials are stable until the manufacturer’s expiration date.
       4.2.2. Room temperature storage (15-30°C) is optional. Re-dating is necessary if stored at room temperature. The QC is good for a maximum of 4 weeks at room temperature, but must never exceed the manufacturer’s expiration date.
       4.2.3. The quality control product should never be exposed to temperatures in excess of 37°C.
4.2.4. Reconstituted vials should be used immediately.

5. CALIBRATION AND CALIBRATION VERIFICATION

5.1. The HEMOCHRON Signature Elite instruments do not require calibration or calibration verification.

6. MAINTENANCE

6.1. Cleaning

6.1.1. Inspect and clean the cuvette opening as needed. Remove residual dried blood or other foreign matter using water moistened cotton swabs. Remove any residual water with a dry cotton swab. If a disinfectant is needed, use a 0.5\% solution of sodium hypochlorite or a 10\% dilution of household bleach in water. Wipe instrument with a water dampened cloth to remove bleach from the plastic surfaces. Apply solution to clean and disinfect areas contaminated with blood. DO NOT use solvents or strong cleaning solutions as they may damage the instrument’s plastic components. Routine maintenance other than cleaning is not required.

6.2. Correlation Data/Method Comparison

6.2.1. The HEMOCHRON Signature Elite instruments are verified to each other every six months by performing testing on samples with different levels of heparin on each instrument. Results must be within 20\% of each other.

6.3. New Instrumentation

6.3.1. Accuracy and precision studies must be completed by running 2 levels of liquid QC by the POCT staff.

6.3.2. A Correlation needs to be performed with an existing instrument by the POCT staff.

7. QUALITY CONTROL

7.1. Self-Check

7.1.1. The HEMOCHRON Signature Elite instrument performs a “self-check” every time it is activated and a test is performed. When a test is initiated by inserting a cuvette, system checks are automatically performed and include:

7.1.1.1. Verification of adequate battery power to complete a full test.

7.1.1.2. Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.

7.1.1.3. Verification that the cuvette temperature is warmed to 37°C +/-1.0°C. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.

7.1.1.4. Verification that the sample is present and is of sufficient size to run test. This insures that the pumps and sample sensing LEDs are functioning properly and that the cuvette is adequately sealed. If these instrument and sample parameters are not appropriate, the test is terminated and an error message displayed.

7.1.1.5. Verification that the internal timers function correctly for each test. If the system timer and assay timer disagree, a real-time clock error message is displayed and the test result is not reported.

7.2. ELECTRONIC QUALITY CONTROL (EQC)

Electronic Quality control must be performed every 8 hours of operation. Internal EQC will check two levels of QC plus the temperature and store the results.

7.2.1. Auto EQC will run automatically if the instrument is plugged in.

7.2.2. To perform manual EQC testing:
7.2.2.1. Display the QC status menu by pressing the QC key before a cuvette is inserted.
7.2.2.2. Press 1. The test chamber warms to temperature and the EQC testing begins.
7.2.2.3. When the test is completed, the results are displayed on the screen and stored electronically.
7.2.3. If results are in range, proceed with patient testing.
7.2.4. If results fail, do not perform patient testing, contact the POCT Department at 272-0980.

7.3. LIQUID QUALITY CONTROL (LQC)

7.3.1. Each lot of test cuvettes should be validated for performance at two liquid quality control levels:
7.3.1.1. When a new shipment is received, and
7.3.1.2. Once per 30 calendar days thereafter.

7.3.2. To perform LQC testing:
7.3.2.1. Remove the cuvettes and directCHECK® vials to be tested from the refrigerator and allow to come to room temperature. (This can take up to 60 minutes)
7.3.2.2. Visually inspect the glass vial and ensure the ampule is intact.
7.3.2.3. After all components have reached room temperature, insert the ACT cuvette into the instrument. NOTE any error messages during this warming period.
7.3.2.4. Select “QC”, the level, and the lot number.
7.3.2.5. The instrument will signal when ready with an audible beep and display “Add Sample” and “Press Start”.
7.3.2.6. Remove the plastic seal from the directCHECK® vial and insert vial into the white protective sleeve.
7.3.2.7. Holding the vial upright, tap the directCHECK® vial on the table to settle the contents.
7.3.2.8. Crush the inner glass ampule by bending the vial over the edge of the table or by crushing between two fingers.
7.3.2.9. Immediately repeat this crushing action two more times to ensure complete breakage of the inner ampule.
7.3.2.10. QUICKLY invert the dropper vial end to end 10 times.
7.3.2.11. While inverting the dropper, (with tip down) use a snapping motion or tap the vial on a counter to move material into the dropper tip.
7.3.2.12. Remove and retain vial cap. Squeeze the vial and discard the first drop of control material into the vial cap.
7.3.2.13. Immediately dispense as many drops of control material as needed to fill the cuvette inner well flush to the top. Should a large “dome” extend over the top, push it over into the outer sample well using the dropper tip.
7.3.2.14. Press the START key.
7.3.2.15. Recap the control vial, remove from white protective sleeve and discard appropriately.
7.3.2.16. Instrument will beep when results are complete. Results are displayed as Pass or Fail. Results are maintained electronically.
7.3.3. If results are within range, proceed with patient testing. Document initial LQC testing on each box in shipment.

7.3.4. If results are out of range, the following items should be verified immediately before repeating:
   7.3.4.1. Control and cuvette expiration dates.
   7.3.4.2. Instrument temperature.
   7.3.4.3. Proper technique.
   7.3.4.4. Cuvette sample volume.
   7.3.4.5. Presence of clots in the control material.

7.3.5. If none of the above parameters are suspect, repeat the test using a new dropper vial of control material.

7.3.6. If the repeat does not fall within the expected range, do not perform patient testing; notify the POCT office at 272-0980 for assistance.

8. PATIENT MANAGEMENT
   8.1. Patient Identification
      8.1.1. Patient identification may be the patient’s name, date of birth, medical record number or assigned trauma alert name, according to UH policy.
      8.1.2. The University of New Mexico Health Sciences Center (UNMHSC) does not recognize a patient’s social security number or room number as a patient identifier.

8.2. Patient Preparation
   8.2.1. The operator must describe to the patient the purpose and the steps of the procedure before testing can begin.

9. SPECIMEN COLLECTION AND HANDLING
   9.1. Standard precautions apply to all Point-of-Care tests.
   9.2. Testing personnel should handle all patient samples as per the Bloodborne Pathogen Exposure Plan.
   9.3. Do not collect patient sample until the test cartridge has been pre-warmed and the instrument displays “Add sample” and “Press Start”.
   9.4. Do not collect fresh whole blood samples using glass blood collection tubes.
   9.5. Do not obtain blood from a heparinized access line, lock or indwelling heparin lock.
   9.6. The HEMOCHRON Jr. ACT-LR or ACT+ tests are performed using 0.05cc of fresh, whole blood. The cuvettes require a minimum sample of 15 microliter to perform the analysis and will display “sample too small” if quantity not sufficient.
   9.7. Samples with any of the following characteristics will generate erroneous results and should not be used:
      9.7.1. Samples contaminated with Tissue thromboplastin.
      9.7.2. Samples contaminated with IV solutions.
      9.7.3. Samples contaminated with Alcohol cleaning solution.
      9.7.4. Samples with visible clotting or debris.
      9.7.5. Unsuspected anticoagulation with either heparin or warfarin.
   9.8. Syringe sample, from venipuncture
      9.8.1. Should have a 23 or larger gauge needle for blood collection. Do not use excessive force when expelling the specimen through the needle as this may cause hemolysis.
9.8.2. Clean venipuncture site with alcohol or other approved method and allow to dry.
9.8.3. Using a two-syringe technique, fill the first non-anticoagulated plastic syringe with 2.0mL of blood and discard.
9.8.4. Obtain at least 0.2 cc of blood sample in a second non-anticoagulated plastic syringe.

9.9. Syringe sample, from indwelling line
9.9.1. Clear line of any anticoagulants or other contaminants by flushing the line with a minimum of 5cc of blood. Longer lines will require more volume to remove contaminants.
9.9.2. After flushing the line and sample port, obtain at least 0.2 mL of blood sample in a non-anticoagulated plastic syringe.

10. SPECIMEN LABELING
10.1. ACT test samples must be analyzed at the patient’s bedside immediately after collection and then discarded. Specimen labeling is not required.

11. PATIENT TESTING
11.1. Insert the cuvette into the instrument, allowing it to pre-warm.
11.2. Scan in the operator’s ID number
11.3. Scan or type in patient’s ID number.
11.4. Observe the instrument for any warning messages or errors during this period.
11.5. The instrument will signal when ready with an audible beep and the screen will display “Add Sample” and “Press Start”. It will remain in this mode for 5 minutes. If the cuvette is not used within 5 minutes, at the end of 5 minutes, a “start timeout” will occur indicating the cuvette must be discarded and a new one obtained for testing.
11.6. Obtain the specimen as described in the specimen collection section.
11.7. Immediately dispense one drop of fresh, whole blood into the sample well of the test cuvette (this may be done with or without a transfer needle) filling the well flush to the top. Should a large “dome” extend over the top, push it over into the outer sample well.
11.7.1. When transferring blood into the sample well, do not force blood into the pin located in the sample well, and do not generate air bubbles in the sample well.
11.8. Press the “Start” key.
11.9. The instrument will beep when results are complete. Results are displayed as the Celite equivalent clotting time.
11.10. All used cuvettes should be considered as potentially infectious, handled with care and disposed of properly.

12. REFERENCE RANGE
12.1. All POC testing done in the hospital has a normal reference range validated with those tests performed on laboratory instruments. The normal range thus correlates to that of the laboratory, if the duplicate testing of the POCT instrument to the laboratory instrument is equivalent.
12.2. ACT testing is performed exclusively at the point of care and not in the laboratory. Thus, there is no normal range to validate against.
12.3. In settings where ACT testing is performed, patients are undergoing procedures in which anticoagulation therapy is necessary. These patients are on heparin therapy and the degree to which they are anti-coagulated is measured both by visualization as well as ACT testing.
12.4. As testing is not performed on a “normal” population, a “normal range” study was deemed as not relevant and the range supplied by the manufacturer is deemed as sufficient.

12.5. See ranges below.

13. CRITICAL VALUES

13.1. All ACT tests are performed under the direct supervision of a physician and results are reported immediately. Critical values are patient dependent.

14. RESULT REPORTING

14.1. Patient results should be immediately recorded in the permanent medical record.

14.2. Since the physician is present during the analysis of blood specimens, results are reported immediately.

14.3. Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be immediately repeated.

15. INTERFERING SUBSTANCES AND LIMITATIONS

15.1. Protease inhibitors such as aprotinin, which may be administered to reduce post-operative bleeding, especially during cardiopulmonary bypass surgery, can prolong the ACT-LR test. Do not use ACT-LR cartridges on patients receiving aprotinin.

15.2. The Hemochron ACT is intended for use in monitoring patients receiving heparin anticoagulation therapy. Values less than 65 seconds or exceeding 1005 seconds are outside the reportable range of the instrument. Test results greater than 1005 seconds should be considered beyond clinical significance and should be immediately repeated.

15.3. ACT test results are affected by poor technique during blood collection and the transfer of the blood to the test cuvettes. Tests may be affected by any of the following conditions:

15.3.1. Foaming of the sample (air bubbles).

15.3.2. Hemolysis.

15.3.3. Clotted or partially clotted blood.

15.4. DO NOT use cuvettes past their expiration date or cuvettes that have been stored improperly.

15.5. DO NOT expose the instrument to extremes in temperature (above 37°C).

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

NORMAL REFERENCE RANGES:
ACT-LR Normal volunteer donors 113-149 seconds
ACT-LR Hospitalized patients not receiving heparin 89-169 seconds

ACT+Normal volunteer donors 81-125 seconds
ACT+Hospitalized patients not receiving heparin 89-169 seconds

CRITICAL RANGE: Patient dependent

REPORTABLE RANGE: ACT-LR 65-400 seconds
ACT+ 65-1005 seconds
CLIA Classification  Moderate
Use  Definitive
If definitive, how will results be used?  ACT is used to monitor all levels of heparin anticoagulation therapy.

SUMMARY OF CHANGES
Updated QC requirements per shipment of cuvettes and documentation on each box of cuvettes and fixed formatting.

RESOURCES/TRAINING

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DOCUMENT APPROVAL & TRACKING

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<td>Matthew Luke, MD; Rapid Response Laboratory</td>
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<td>Erin Doles, Administrator, Professional &amp; Support Services</td>
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