ACTIVATED CLOTTING TIME BY HEMOCHRON SIGNATURE ELITE

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<th>DATE PREPARED:</th>
<th>February 1999</th>
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<td>DATE ACCEPTED:</td>
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| ACCEPTED BY:  | Dr. James Cotelingam  
                Medical Director of LSUHSC Clinical Laboratory |
| REPLACES:     | Not Applicable |
| REVIEWED BY:  |               |

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<tr>
<th>REVIEWED: DATE</th>
<th>COORDINATOR</th>
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<td>3/01</td>
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<td>Institution name updated.</td>
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<td>3/03</td>
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<td>Procedure upgrade due to model upgrade to Signature Plus</td>
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<td>p. 10 Re-established testing in Special Procedures and addition of SICU / BURN Unit to procedure</td>
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I. **TITLE: ACTIVATED CLOTTING TIME - HEMOCHRON SIGNATURE**

II. **PRINCIPLE**

The Hemochron Signature utilizes a mechanical endpoint clotting mechanism in which testing occurs within the disposable ACT cuvette. Following whole blood sample introduction, the instrument precisely measures 15 microliters of blood and automatically moves it into the test channel within the ACT 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 then 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 microcoagulation 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 causing the instrument’s timer to display the coagulation time in seconds. The whole blood ACT test result is displayed by the instrument’s digital timer as the celite equivalent ACT value in seconds in order to provide a familiar clinical format and thus facilitate accurate clinical test result interpretation.

Monitoring heparin therapy is necessary during various medical and surgical procedures to maintain hemostasis during the procedure. Without optimal anticoagulant therapy, undesirable side effects can happen. Close monitoring and control of anticoagulation is desirable to ensure clot free blood flow while minimizing bleeding complications following the surgical procedure. It is most commonly used for heparin anticoagulation monitoring during bypass surgery, Percutaneous Transluminal Coronary Angioplasty (PTCA), Interventional Radiology, neonatal Extracorporeal Membrane Oxygenation (ECMO), hemofiltration, hemodialysis and critical care (CAVH- Continuous Arterial to Venous Hemodialysis and CVVH- Continuous Venous to Venous Hemodialysis).
III. SPECIMEN REQUIREMENTS

A. Handling:

NOTE: Blood samples must not be collected until the instrument display indicates “Add Sample” and “Press Start”.

B. Requirements:

The ACT test is optimally performed using 0.05cc of fresh whole blood. The cuvette requires a minimum volume of 15µl to perform the analysis, and will display a “Sample too small” if insufficient sample is applied. Samples with any of the following characteristics should be discarded immediately, and a fresh whole blood sample collected prior to performing any test:

- Sample contamination with tissue thromboplastin.
- Sample contamination with indwelling intravenous (i.v.) solutions.
- Sample contamination with alcohol cleansing solution.
- Samples with visible clotting or debris accumulation.

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

C. Collection Procedure:

If a syringe is used, it should have a 23 gauge needle or larger. DO NOT use excessive force when expelling the blood specimen through the needle. This may lead to sample hemolysis.

Blood samples to be used for coagulation testing must be collected according to the following procedures to assure the integrity of the fresh whole blood sample.

**Syringe sample, from indwelling line:**

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 heparin lock will require approximately 5 cc to clear the line. Greater volumes will be required to clear longer lines. Do not collect the blood sample using glass collection tubes.

1. Using a 1cc (tuberculin) or 3cc syringe, collect a minimum 0.20 cc of fresh whole blood from a previously flushed access port. Do not allow bubbles to form in the syringe.
2. **Immediately** dispense one drop of fresh whole blood into the sample well of the test cuvette, filling from the bottom of the well up. This may be done either with or without a transfer needle. A sufficient quantity of blood must be added directly to the center of the sample well to fill it flush to the top. Should a large drop of blood extend above the top of the center sample well, push it over into the outer sample well.

**Syringe sample, from a venipuncture**

1. Prepare the venipuncture site by cleansing with alcohol and allowing to air-dry completely.
2. Using a two-syringe technique, fill the first syringe with 2.0 cc of blood and discard.
3. Obtain a minimum 0.20 cc of blood with the second syringe.
4. Immediately dispense one drop of blood into the center sample well of the test cuvette, filling from the bottom of the well up. This may be done either with or without a transfer needle. A sufficient quantity of blood must be added directly to the center of the sample well to fill it flush to the top. Should a large drop of blood extend above the top of the center sample well, push it over into the outer sample well.

**IV. INSTRUMENTATION AND SUPPLIES**

1. Hemochron Jr. Signature Elite Microcoagulation Instrument’s timing range is 0-1,005 seconds per Operator’s Manual.
2. Electrical Charging cord
3. Plastic syringe (1cc or 3cc) with a 23 gauge or larger transfer needle (optional)
4. directCHECK Whole Blood Quality Controls – store in refrigerator at 2-8°C. Allow to reach room temperature (15-30°C) which may take 15 – 60 minutes.
   - **DCJLR-N** - Normal Level for ACT-LR
   - **DCJLR-A** - Abnormal Level for ACT-LR
   - **DCJACT-A** - Abnormal Level for ACT+
   - **DCJACT-N** - Normal range for ACT+
5. Fresh whole blood sample
6. ACT+ cuvettes – a self contained disposable test chamber preloaded with a dried preparation of kaolin, phospholipid, stabilizers and buffers. Each cuvette is individually packaged in a foil pouch with a dessicant. Each box contains 45 individually pouched cuvettes. Cuvette pouches are stamped with a lot specific expiration date.
7. ACT-LR cuvettes – a self contained disposable test chamber preloaded with a dried preparation of celite, potato dextrin, stabilizers and buffers. Each cuvette is individually packaged in a foil pouch with a dessicant. Each box contains 45 individually pouched cuvettes. Cuvette pouches are stamped with a lot-specific expiration date.
**Storage:** Cuvettes must be at room temperature prior to use. For cuvettes stored at refrigerated temperature, this may take up to 60 minutes. When refrigerated (2-8°C), the foil-pouched ACT cuvette is stable until the marked expiration date. Room temperature storage (15-30°C) is optional for sealed-pouched cuvettes. **Room temperature cuvettes are good for a maximum of 3 months for ACT+ and 3 months for ACT-LR, but must never exceed the marked expiration date.** Re-dating is necessary if stored at room temperature. A re-dating label is included on the side panel of each box of cuvettes and should be completed. DO NOT expose to temperatures in excess of 37°C.

**Caution:** All used cuvettes should be considered as potentially infectious, handled with care and disposed of by following standard waste disposal policy.

V. **CALIBRATION**

Not Applicable.

VI. **PROCEDURE**

**NOTE:** Press QC Key to check status (Cancel to exit screen). Instrument will display time left before next required EQC. Appropriate Personal Protective Equipment should be worn when collecting specimens, preparing reagents/specimen and performing testing.

**A. Electronic Quality Control (EQC)**

EQC Must Be Performed Every Eight Hours of operation.

1. When instrument is OFF, press green Start button to start EQC. Instrument will warm to desired temperature, and then perform a 30-second Normal QC and continue running to 500-seconds for the Abnormal QC.
2. Once both Target Levels (30 seconds for Normal QC and 500 seconds for Abnormal QC) have been reached, the instrument will display:

   L1=30 Sec. PASS  
   L2=500 Sec. PASS  
   Temp=37.0 C PASS  
   EQC PASSED  
   “Test Completed” and “CANCEL to Exit” will alternately be displayed.

**Note:** The temperature should be 37° ± 1°C. PASS on Temp indicates that the temperature control system is functioning normally and within range.
3. Pressing CANCEL will cause INSERT and CUVETTE to be alternately displayed.

4. If instrument is plugged into the electrical outlet, and Start is pressed, the meter will automatically perform EQC every 8 hours. 
   **NOTE:** A cuvette left in instrument will cause Blocked Sensor to display—must remove cuvette for EQC to run.

5. All QC information is stored in the instrument memory

   **NOTE:** An acceptable test result without fault indicators for the system verification cartridge assures that the instrument is functioning properly. If any electronic QC procedure yields an on-screen ERROR message, or if the electronic system failed to yield the desired results, re-run the EQC by pressing the green Start button. Instrument is set to Lockout with 4 failed QC results obtained. Discontinue use of the instrument for patients and contact the POC area at ext. 57951 or 55572. Loaner meter may be obtained from the Clinical Laboratory Front Office on 2nd Floor after hours, and on weekends and holidays.

B. Patient Testing

   **NOTE:** Both levels of EQC must be acceptable before running patient test.

1. **Insert** a Cuvette into the right side of instrument. Instrument displays **Cuvette Lot**…. Press & hold PRINT/SCAN button and scan cuvette package barcode. Instrument will beep and briefly display “Lot stored”. 
   **DO NOT force a cuvette into the instrument.**
   **DO NOT use expired cuvettes.**

2. Instrument will display **Enter OID** (Operator ID). Press & hold PRINT/SCAN button and scan Operator badge barcode.

3. Instrument will display **Enter PID** (Patient ID). Press & hold PRINT/SCAN button and scan inpatient’s armband with 110-account number or manually enter the outpatient’s 106-account number. (If manually entering, press & hold ENTER button.) Instrument will audibly beep and briefly display “Stored”.

4. **TAKE INSTRUMENT TO BEDSIDE.** The instrument will remain in the ready mode for five minutes.
5. Instrument displays *Add Sample…Press Start* and the five-minute countdown clock will begin to allow time for specimen collection.  
**NOTE:** If specimen is not introduced by the end of five minutes, a “Start timeout” will occur indicating that the current cuvette be discarded and a new cuvette placed in the instrument.

6. Waste 5 cc blood to clear either Venous or arterial line.

7. Collect 1 cc blood sample from cleared line.

8. Dispense 2 drops of blood into center of cuvette Sample Well being careful not to over- or under-fill Sample Well.

9. Press & hold the green Start button on the instrument.

10. **When complete**, the instrument will beep and display the result.

11. **DO NOT remove cuvette** before result is displayed!

12. **Record test result** on flow sheet/chart.

13. **Remove and discard cuvette** with adherence to Infection Control Guidelines.

14. Every test should be performed using a Fresh Sample.

C. **Liquid Quality Control**

1. Remove the ACT test cuvettes and the directCHECK vials (Abnormal and Normal) from the refrigerator and allow them to come to room temperature prior to testing. This could take up to 60 minutes.

2. After the reagents have reached room temperature, verify that EQC is current. Perform EQC if needed.  
**NOTE:** Both levels of EQC must be acceptable before proceeding to liquid QC test performance.

3. **Insert** a Cuvette into the right side of instrument. Instrument displays *Cuvette Lot…* Press & hold PRINT/SCAN button and scan cuvette package barcode. Instrument will beep and briefly display “Lot stored”.  
**DO NOT force a cuvette into the instrument.**  
**DO NOT use expired cuvettes.**

4. Instrument will display **Enter OID** (Operator ID). Press & hold PRINT/SCAN button and scan Operator badge barcode.
5. Instrument will display **Enter PID**. Press & hold QC button. QC SELECTS will display:

1-QC Normal  
2-QC Abnormal  
3-Patient Result  
4-QC Status  

6. Choose either 1-Normal or 2-Abnormal checking the vial to be certain of choice.

7. QCN Lot List will be displayed. Barcode from the QC should be scanned, or **7 Manual Entry** may be chosen to manually enter the QC lot.

8. Remove the top of the plastic seal from the directCHECK vial.

9. The instrument will signal when ready with an audible beep, and display alternating messages “Add Sample” and “Press Start”.

10. Tap the directCHECK vial on the counter top to ensure that the inner glass ampule is at the bottom of the plastic dropper.

11. Insert the directCHECK vial into the white protective sleeve provided, and reconstitute the contents by crushing the inner ampule either by:
   - Bending the vial over the edge of the table top, or
   - By pressing between two fingers.

12. Immediately repeat this crushing action one to two more times.

13. Quickly invert with cap on and shake the vial 10 times end to end.

14. Remove the vial cap.

15. Using a downward snapping motion of the wrist, invert the vial.

16. Discard the first drop of control material into the vial cap.

17. Squeeze the vial to dispense contents into the ACT cuvette sample well. DO NOT generate air bubbles in the sample well. A sufficient quantity of whole blood control (approximately 50 µl) must be added to fill the center well flush to the top. Should a large drop of sample extend above the top of the center sample well forming a dome, simply push the excess sample over into the outer sample well.

18. Press the START key.

19. Wait for a single beep signaling the conclusion of the test.  
   **NOTE:** Two beeps indicate a fault condition.

20. Results are displayed as the celite equivalent clotting time. Report results.

21. Compare the result with the acceptable range for each level of quality control reagent as published on the back page of the package insert in each box of quality control material. (These ranges are Lot # specific and may vary slightly from lot to lot.)
VII. **CALCULATIONS**

Not Applicable.

VIII. **QUALITY CONTROL**

A. **Electronic Quality Control (performed by testing personnel):**

Electronic System Verification Cartridges at the normal and abnormal range must be performed once every 8 hours on any shift during which the instrument is utilized.

*Acceptable Results:*
Run patient samples.

*Unacceptable Results:*
1. Repeat control(s).

If results are still unacceptable, contact POC at ext. 57951 or 55572. If it is after hours, on a weekend or holiday, a loaner is available at the 2nd floor Laboratory Office.

B. **Liquid Quality Control by POC Personnel or Testing Personnel:**

Each box of test cuvettes must be validated upon its receipt before being placed into use for patient testing. Two levels, Normal and Abnormal, are used. Both levels of *directCHECK* must be acceptable prior to being placed into use.

*Acceptable Results:*
Document. Cuvettes are ready for use.

*Unacceptable Results:*
- Verify cuvette expiration dates. If liquid controls are out of range, verify their expiration dates and that there are no clots.
- Check for instrument temperature fault.
- Verify proper technique was used.
- Check cuvette sample size.
- If liquid controls are unacceptable, try new controls.
- If results are still unacceptable, try another box in the shipment.
- If results are still unacceptable, contact Technical Support to check on shipping problems.

Additionally, Liquid Quality Control will be performed monthly by testing personnel.
IX. RESULTS

Results that exceed “400” seconds must be reported out as greater than 400 seconds when using ACT-LR cuvettes.

ACT+ cuvettes are approved for use in the OR. Results that exceed “700” seconds must be reported out as greater than 700 seconds.

A. Critical Values:
NOTE: Test results less than 50 seconds or greater that 300 seconds must be repeated, or must correlate with patient condition, and/or treatment. All results are entered in the nurses notes/procedure notes/flow sheet as part of the patient record. Critical values require immediate physician notification and documentation. EXCEPTION: OR area.

MICU
CVAH/CVVH or ECMO - initial lab drawn and sent to Clinical Laboratory. No initial baseline is performed. Activated Clotting Time performed hourly thereafter as per physician orders.

Returning CATH Patients - initial Activated Clotting Time performed per CATH LAB instructions. Additional testing performed as directed. Once desired level is achieved, CATH LAB notified and testing discontinued.

B. Therapeutic Ranges:

NOTE: Therapeutic Ranges were established:
1. through manufacturer supplied statistical data and
2. consultation with faculty physicians.

Ranges are based on procedure and overall outcome. Authorized medical personnel may alter ranges during a procedure when required.

MICU: CVVH_______________200-225 secs
       ECMO_________________180-200 secs

Monitoring of post CATH LAB procedures is performed to monitor clotting levels for safe removal of arterial and venous sheaths. Target range identified and recorded in patient chart by CATH LAB personnel. MICU personnel may notify CATH LAB when target range achieved to initiate sheath removal procedure.
RENAL UNIT
Tight Systemic Monitoring:
* Prior to heparin dosing, a baseline sample is drawn and tested.
* Test result is multiplied by 1.25 to determine target value.
  Target range generally 160-180 secs unless specified differently by physician.
Routine Heparin Monitoring:
  Target range generally 200-260 secs unless specified differently by physician.

SPECIAL PROCEDURES:
Target value during procedure >300 secs.
Target value during sheath removal <175 secs.
Neuro Interventional Lab=Therapeutic range 250-350 sec.

PICU / SICU / BURN UNIT:
Normal ranges are patient- and physician-specific depending upon clinical case. Physicians indicate acceptable ranges in patient charts. Results outside acceptable ranges are reported to physician and/or physician indicated response is performed.

OR:
- Bypass Surgery Procedure________>450 secs
  with Roller Head Pump
- Bypass Surgery Procedure________200-250 secs
  with Centrifugal Pump

  Monitoring is performed as deemed necessary by Perfusionist with dosing being adjusted as required.

CATH:
During procedures............Target Range 200 – 400 secs or w/Repo 225 – 275 secs
Sheath removal in
Cath Recovery Room or MICU...Target Value 150 secs

Monitoring is done approximately every 15 minutes during procedures with the heparin dose being adjusted in accordance with ACT results.

X. PROCEDURE NOTES
1. Any instrument problem must be reported to POC at ext. 57951 or 55572. If it is after hours, on weekend or holiday, a loaner is available at the 2nd floor Laboratory Office
2. DO NOT use cuvettes past their expiration date or cuvettes that have been improperly stored.
3. **DO NOT** force a cuvette into the instrument. If resistance to insertion is encountered, gently remove the cuvette and examine the cuvette slot. Remove any obstruction before attempting further use of the instrument. If unable to remove easily, contact POC at ext. 57951 or 55572.

4. **DO NOT** use excessive force in depressing the START key.

5. **DO NOT** drop the instrument. If dropped, perform electronic quality control (QC). If QC is acceptable, instrument can be used. If unacceptable, contact POC at ext.57951 or 55572.

6. **DO NOT** expose instrument to extreme temperatures (above 37°C).

7. Use only Hemochron test cuvettes assigned to the area. Supplies must be obtained via POC. **Inventory must be checked by testing personnel** at least weekly to avoid shortages.

8. Results should be scrutinized in light of a specific patient’s condition or anticoagulant therapy. Any test result exhibiting inconsistency with the patient’s clinical status should be repeated or supplemented with additional diagnostic tests.

9. All institutional guidelines must be strictly adhered to when collecting specimens or operating the instrument.

10. **The instrument must be disinfected with a 10% bleach solution** moving from patient to patient, leaving the unit or contaminated. Bleach must be applied to a clean towel or cloth. **DO NOT** pour onto any part of the instrument. If the instrument requires excessive decontamination, contact POC at ext. 57951 or 55572 for assistance.

11. POC personnel perform advanced troubleshooting and repair. All supplies, including batteries, must be obtained through POC personnel at ext. 57951 or ext. 55572.

12. **Low Battery** indicates that the instrument needs to be plugged into the wall for recharging.

13. **Common faults:**
   - Sample not seen – Repeat test.
   - Sample too large – Repeat test.
   - Sample too small – Repeat test.
   - Bubbles in sample – Repeat test.
   - Pump fault – Repeat test. If repeats, contact POC at ext. 57951 or ext. 55572.
XI. **LIMITATIONS OF PROCEDURE**

1. Interfering Substances: Aprotinin is an antifibrinolytic drug often administered during cardiac surgery in order to prevent post surgical bleeding complications. The celite ACT is artificially prolonged while the kaolin ACT (including the ACT+) is not affected by antifibrinolytic therapy (e.g., aprotinin), except at very high (>500 KIU/cc) concentrations.

2. The **ACT-LR** test is intended for use in monitoring patients receiving heparin anticoagulation therapy who attain a blood heparin concentration of up to 2.5 units of heparin/cc of blood. Values exceeding 400 seconds are reported as >400 seconds.

3. The **ACT+** test is intended for use in monitoring patients receiving heparin anticoagulation therapy who attain a blood heparin concentration of more than 1.0 unit of heparin/cc of blood, but less than 6.0 units of heparin/cc of blood. Results less than 67 seconds are reported as <67 seconds. Results exceeding 700 seconds are reported as >700 seconds.

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

5. 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 a reference ACT, actual differences of clotting time may be observed.

6. The effect of agents such as aspirin, tranexamic acid, DDAVP, anti-fibrinolytics, defibrinating agents (e.g., Ancrod), direct thrombin inhibitors (e.g., ReoPRo, Eli Lilly and Co., Centocor B.V.) on the ACT+ may be different than those on the reference ACT.

XII. **REFERENCES**


XIII. **DISTRIBUTION**

This procedure is on file in the Point-of-Care section of the Clinical Laboratory and in the LSUHSC-Shreveport website.