HEMOCHRON SIGNATURE ELITE
LOW RANGE ACTIVATED CLOTTING TIME (ACT-LR)

READ POLICY PRIOR TO STARTING TUTORIAL
Before Testing a Patient

- ORIENT YOURSELF TO YOUR WORKING AREA
  - Locate HEMOCHRON Signature Elite Microcoagulation Instrument
  - Locate testing supplies:
    - Liquid Quality Controls:
      - Level 1, Normal
      - Level 2, Abnormal
    - PC Cable
    - AC/DC power supply
    - Battery
    - HEMOCHRON Signature Elite Operator’s Manual
    - HEMOCHRON Jr. Whole Blood Microcoagulation Systems ACT-LR package insert
    - HEMOCHRON ReportMaker V6.0 or higher CD (Data Management Software)
    - IDA page for your nursing unit.
Qualified Personnel

- Testing personnel are required to take the Initial Orientation and Training, the Initial Competency Exam, Methods of Competency and a second Competency Exam within the first year.

- Competency Exams are then required annually thereafter.

- Clia ‘88 requires staff to have a high school diploma or a college degree in one of these listed sciences to perform this moderately complex test. Please submit a copy of your HS Diploma or College Degree in Chemical Science, Biological Science, Physical Science (or Nursing) to POCT Services.
Operator Barcodes

- Upon completion of the Initial Orientation and Training, 6 Methods of Competency, and Written Exam, staff will be issued a barcode ID to be able to use the StatSensor Creatinine meters.

- This barcode is embedded with unique identifiers specific to each staff member.

- **NEVER** share your Barcode ID!
Using the HEMOCHRON Signature Elite Microcoagulation instrument is considered **Moderate** in complexity by the FDA.

**PURPOSE:** The HEMOCHRON Signature Elite, ACT-LR is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. It is intended for use in monitoring low to moderate heparin doses frequently employed in procedures such as cardiac catheterization, extracorporeal membrane oxygenation (ECMO), hemodialysis, and Percutaneous Transluminal Coronary Angioplasty (PTCA). The ACT-LR test is for *in vitro* diagnostic use and is for use with any model HEMOCHRON Whole Blood Microcoagulation System.
Universal Precautions should be observed through all phases of the testing procedure.

**Samples should be fresh whole blood.** (Do not obtain blood from heparinized access line, lock, or indwelling heparin lock.)
Specimen

☐ Syringe sampling from **indwelling line**: Flush the line thoroughly.

  ▪ Using 3 cc syringe, fill the syringe with 2 cc of blood and discard.
  ▪ Using a tuberculin (1 cc) syringe, collect 0.2 cc of blood (do not allow bubbles to form in the syringe) and immediately dispense one drop of blood into the sample well of the test cuvette; filling from the bottom of the well up.
  ▪ A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top. Should a large drop of blood extend above the center sample well, push it over into the outer sample well.

☐ **Stability**: Sample needs to be tested immediately.
Specimen

- Syringe sampling from a **venipuncture**:
  - Prepare the venipuncture site by cleansing with alcohol and allowing to air dry completely.
  - Using a two syringe technique fill the first syringe with 2 cc of blood and discard.
  - Obtain 0.2 cc of blood with the second (1 cc tuberculin) syringe and immediately dispense one drop of blood into the sample well of the test cuvette; filling from the bottom of the well up.
  - A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top. Should a large drop of blood extend above the center sample well, push it over into the outer sample well.
HEMOCHRON Jr. ACT-LR Test Cuvettes

- Test cuvette is 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 pouch.
- **Cuvette pouches are stamped with a lot-specific expiration date.**
Storage and Stability:

- When refrigerated (2-8°C), the foil pouched ACT-LR cuvettes are stable until the marked expiration date.
- Room temperature storage (15-30°C) is optional for unopened, pouched cuvettes. ACT-LR cuvettes should not be exposed to temperatures in excess of 37°C.
Quality Control testing of the HEMOCHRON Signature Elite consists of the following operations:

- Testing system performance and verifying system temperature using internal Electronic System Verification every eight hours of operation.
- Testing cuvettes in accordance with the Package Insert for each assay using two levels of Liquid Quality Controls.
Quality Control

Self-Check:

- The HEMOCHRON Signature Elite instrument performs a “self-check” every time it is activated and a test is performed.
- Verification of adequate battery power to complete a full test.
- Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.
- Verification that the cuvette temperature is warmed to 37°C ± 1°C.
- Verification that the sample is present and is of sufficient size to run test.
- Verification that the internal timers function correctly for each test.
Quality Control

- Verification of Instrument Temperature:
  - Instrument temperature is automatically checked whenever EQC is carried out. The instrument temperature check verifies that a temperature of \(37^\circ C \pm 1^\circ C\) is maintained during the test.
Quality Control

- Electronic Quality Control – Performance:
  - The instrument should be tested at two levels (normal and abnormal) once every eight hours of operation. **Automatic** internal Electronic Quality Control (EQC) is used to provide a two-level electronic verification of instrument performance.
  - EQC is performed automatically (every 8 hours) if the instrument is plugged into the AC/DC Power (and has been preprogramed through the Configuration Manager programming). The results are stored to the database and displayed for five minutes (or until “Cancel” is pressed).
  - The EQC can be performed manually (in addition to automatically).
Quality Control

- EQC steps (manually):
  - Press the QC key **before** a cuvette is inserted.
  - Press 1-EQC. The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing.
  - When the test is completed, the results are displayed on the screen and written to the QC database. Press “Cancel” to exit the screen.

- NOTE: EQC tests two levels (Normal level 30 seconds and Abnormal level 300-500 seconds) of QC and the temperature. If one level fails, the test will stop and record all results as failed. If the user aborts the internal EQC test, the test is not saved to the database or printed.
Quality Control

- QC of Reagents (Cuvettes) –

Liquid Quality Control – Performance:

- Cuvette validation is carried out using the appropriate HEMOCHRON Jr. Microcoagulation Whole Blood Liquid Quality Control products (LQC).

- Acceptable performance ranges for the cuvettes are included with each HEMOCHRON QC product (package insert located in the LQC box).

- The cause of out-of-range results is likely attributable to test technique, control material, cuvette and/or the instrument.
Cuvettes should be validated for performance at two LQC levels (Level 1 = normal and Level 2 = abnormal):

- When a new shipment is received, and
- Once per 30 calendar days thereafter
LQC steps:

- The cuvette and the LQC material must be at room temperature. **Allow up to 60 minutes for warming, if cuvettes and LQC material were stored in the refrigerator.**
- Visually inspect each vial to insure that the glass ampule inside the plastic vial is intact.
- Insert a cuvette into cuvette slot on instrument.
Quality Control

- Scan cuvette lot number.
- Scan directCHECK lot number by pressing SCAN or SELECT current lot number if stored on Hemochron.
- Press QC, select **QC NORMAL** or **QC ABNORMAL** (Run NORMAL LQC first, then repeat these steps for ABNORMAL LQC).
- Scan Operator Bar Code ID.
- Instrument will signal with an audible tone and display “Add sample...Press Start”.
Quality Control

- Reconstitute the LQC vial (this must be done quickly).
- Remove shrink wrap from vial.
- Insert normal directCHECK vial into white protective sleeve.
- Holding the vial upright, **tap the directCHECK vial on the table top to settle the inner glass ampule to the bottom of the vial.**
- Crush inner glass ampule by bending the vial over the edge of a table top, or crushing between two fingers.
Quality Control

- Repeat action 2-3 times to ensure vial is completely crushed.
- Quickly invert dropper vial end to end 10 times and use a downward snapping motion of the wrist to ensure the control material flows to dropper tip.
- Remove and retain vial cap.
- Squeeze vial to discard the 1st drop of LQC into vial cap.
Quality Control

- Dispense LQC as needed to fill cuvette sample well flush to top.
- Immediately press the “START” key.
- Remove control vial from protective sleeve.
- Dispose vial and vial cap appropriately.
- Retain protective sleeve for reuse.
Quality Control

- Wait for single beep to signal end of test.
- Results will be displayed as ACT Celite-equivalent seconds.
- If LQC ranges were not programmed into instrument, compare the result to the package insert (Ranges are lot number-specific).
- Record results.
- Repeat same steps for ABNORMAL LQC.
Patient Testing

- Before patient testing, let cuvette (that has been Quality Control checked) come to room temperature (15 – 30 °C). Allow about 60 minutes of warming, if the cuvettes were taken from the refrigerator.

- Start the instrument by holding down the “START”.

- Insert cuvette with label facing up and push it all the way in until it stops.

- The instrument will signal when “ready” with an audible tone.
Patient Testing

- Scan cuvette lot number.
- Scan the operator Bar Code ID.
- Scan or manually enter the patient’s Medical Record Number (MRN) as their patient ID (PID). The instrument emits an audible beep after the patient’s ID is scanned and the ID remains displayed along with the name of the test.
Patient Testing

- Once the “ADD SAMPLE”...”PRESS START” messages are displayed you have 5 minutes to:
  - Acquire the sample
  - Fill the sample well
  - Press “START” key

- Obtain blood sample (see sample collection under SPECIMEN).

- Immediately fill the sample well from the bottom up. Add enough blood so that the lower wall of the center sample well is completely filled.
Patient Testing

- Press the "START" key. The elapsed time is displayed in seconds until the sample clots.
- When a clot is detected, the instrument beeps and the final results of the test are displayed as Celite equivalent ACT value seconds (not real time seconds).
- Record results.
- When finished, remove the cuvette and discard.
- To shut down instrument: Press "0" on the keypad to display the "MAIN MENU" and then press "4", or press and hold down the "START" key for 4 seconds.
Reporting / Documentation Results

- Reference range: < 188 seconds (based on a study of 20 healthy SFGH outpatients).

- Heparinized result: > 200 seconds.
  - **Notes**: Whole blood ACT-LR test results less than 65 seconds will result in an “Out of Range-Lo” error message. This may indicate excessive blood coagulation activation and should be repeated to confirm the result.
  - Celite Equivalent Values (CEV) over 400 seconds are not reported on the instrument. Instead, an “Out of range – Hi” message will be displayed. CEV that exceed 400 seconds due to extremely high sensitivity to heparin in the patients do not represent an error in the test.
  - Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be immediately repeated.
Limitations

- The Hemochron Jr. ACT-LR test is intended for use in monitoring patients receiving heparin anticoagulation therapy with low to moderate heparin levels (up to 2.5 units unfractionated heparin / mL). Celite equivalent ACT values over 400 seconds are not reported on the Hemochron system. Instead, an “Out of range – Hi” message is displayed.

- Tests may be affected by any of the following conditions:
  - Foaming of the sample (air bubbles)
  - Hemolysis
  - Clotted or partially clotted blood
  - Unsuspected anticoagulation with heparin or Low Molecular Weigh Heparins (LMWH)
Limitations

- Test results should always be scrutinized in light of a specific patient’s condition and anticoagulation therapy. Any test results exhibiting inconsistency with the patient’s clinical status should be repeated or supplemented with additional diagnostic tests.

- Samples with a hematocrit less than 20% or greater than 55% are not recommended due to an optical density outside the detection level of the Hemochron Signature Elite Microcoagulation instrument. In such cases, a “Sample Not Seen” error message will be displayed.

**MSDS** – Located on the SFGH-POCT.org website under “ACT”
For Further Questions or Information
Contact POCT Services

SFGH-POCT.org