PROCEDURE: ACTIVATED CLOTTING TIME (ACT) Hemochron Signature Elite

ISSUE DATE: March 2013 **REVISION DATE:**

PRINCIPLE:

The portable, battery operated Hemochron Signature Elite is a microcoagulation instrument designed to perform whole blood coagulation test using fresh whole blood at the patient bedside.

The Hemochron Signature Elite utilizes a mechanical endpoint clotting mechanism in which testing occurs within the disposable ACT-LR cuvette. Following whole blood sample introduction, the instrument measures 15 microliters of blood and automatically moves the sample into the test channel within the ACT-LR cuvette. The remainder of the 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 several 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 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 result in seconds to provide a familiar clinical format to faciliate accurate clinical test result interpretation.

SPECIMEN

Whole blood samples to be used for coagulation testing must be collected in the following manner to prevent contamination with tissue thromboplastin, indwelling intravenous (I.V.) solutions or alcohol cleansing solution, which interfere with coagulation assays. Poorly collected blood samples with visible clotting or debris accumulation must be discarded and a fresh sample collected. A syringe-collected specimen is the method of choice for this procedure. When blood is to be drawn by syringe from an IV line, 5cc of blood must be wasted before drawing out the blood specimen for testing. When a syringe is used, it should have a 23 gauge needle or larger. Use of excessive force when expelling the blood specimen through the needle may cause hemolysis.

NOTE: Blood samples for testing should not be collected until the instrument indicates **"ADD SAMPLE" and "PRESS START". There is no storage prior to testing.**

Universal precautions must be observed through all phases of specimen collection and testing.

Venipuncture Sample

1. Using a two syringe technique collect the first 2 mL to remove possible tissue thromboplastin contamination. This first specimen collected may be used for alternative non-coagulation assays.

   Identify patient as directed by SLCH Hospital policy.

2. Obtain a 0.2 cc sample with the second syringe.

3. Immediately dispense one drop of blood into the sample well of the test cuvette. A sufficient quantity of blood must be added directly to the center of the sample well such that the blood overflows into the outer circle of the sample well. This ensures that sufficient blood is available for the test sample aliquoting.

4. Unacceptable specimens include using a citrated tube for collection, pre-heparinized syringe, sample contaminations with tissue thromboplastin, sample contamination with indwelling IV solutions, samples with visible clots and sample contamination with alcohol cleansing solution.

EQUIPMENT:

- Hemochron Signature Elite microcoagulation instrument

REAGENTS:

- Hemochron ACT-LR Cuvettes – ACT test cuvettes are preloaded with a preparation of silica, kaolin, phospholipid, stabilizers and buffers. Each cuvette contains a test channel in which the test is performed and a waste channel into which excess blood is drawn. Caution – All used cuvettes should be considered potentially infectious, handled with care and disposed of with biohazard waste. Cuvettes are good until the printed expiration date as long as they are kept in the refrigerator. The cuvettes must be kept at room temperature for 60 minutes prior to testing. At room temperature, an unopened pouch is good for 12 weeks. ACT-LR cuvettes are packaged one in each foil pouch. Dialysis Testing cuvettes are stored in the Core lab and brought to the Dialysis unit as needed for Quality Control and patient testing. Cath lab is weekly stocked with testing cuvettes. New lots of ACT-LR cuvettes are checked to verify quality by running 2 levels of Hemochron ACT-LR quality control.

- Hemochron Elite Quality Control Kit – Whole blood quality control will be performed by Point of Care to verify quality of new boxes of quality control. Whole blood Quality Control, undiluted, is good until the printed expiration date as long as it is refrigerated. At room temperature, undiluted whole blood quality control is good for 4 weeks.

- All trained and competent Hemochron Elite users will scan their SLCH employee number in the Hemochron when performing patient testing or quality control.

CALIBRATION: There is no calibration of the instrument as calibration is completed by the manufacturer.

QUALITY CONTROL:

Quality Control is reviewed by the Point of Care Coordinator weekly.

Monthly Quality Control is reviewed by the Core lab Medical Director.

All Quality Controls are stored in the Core Lab.

System Self Checks

The Hemochron Elite performs a "Self-Check" every time the instrument is turned on or a cuvette is inserted. These system checks include verification of battery power, LED check, and temperature check.

After the sample is added and the "START" key is pressed, the system continues a self checking process.

It verifies that the sample is present and of sufficient volume to run the test. This ensures that the pumps and the sample sensing LEDS are functioning properly and that the cuvette is adequately sealed. If these criteria are not met, the test will be terminated and an error message is displayed.

Electronic Quality Control

EQC is used to provide a two level electronic verification of instrument performance. The internal time is 8 hours and is performed automatically by the instrument. The instrument is programmed by the Point of Care Coordinator/designee. The EQC can also be performed manually by the operator as needed or at the beginning of the day. Once EQC starts the program cannot be interrupted for patient testing.

> To manually perform the EQC, press the "QC" key. Press "1-EQC". The test chamber warms to temperature and the EQC test begins. Results are displayed on the screen. Record on the EQC logs.

The Internal EQC will check a Normal (30 seconds) and an Abnormal (300 seconds) and also the internal temperature. If one test fails to meet specifications, the EQC will stop and record all results as failed.
If Electronic QC fails and an on screen ERROR message occurs, discontinue all patient testing and use of the instrument. Contact Point of Care at pager 360-7930.

Liquid Quality Control

Liquid Quality Controls must be run once a week by a trained and competent individual in the area of testing to ensure the instrument's operation. Liquid Quality Control must be at room temperature to assay.

Liquid Quality Control is sent weekly to the testing area from the Point of Care testing area. Control Lot numbers are programmed in the Hemochron Elite.

Scan barcode on cuvette package

- Press "QC" soft key
- Select QC level 1-Normal or 2-Abnormal to tag the sample
- Open the cuvette pouch
  Insert into the cuvette slot on the side of the instrument. The instrument will signal when ready with an audible beep, and display alternating messages: "Add sample" and "Press Start"
- Using a protective sleeve, crush vial 2-3 times on the edge of the counter. Invert the dropper vial end to end 10 times and use a downward motion of the wrist to ensure the control material flows to the dropper tip.
  Expel first drop into biohazard container. Immediately dispense 1-2 drops of control material needed to fill the cuvette well.
- Press Start key. Dispose of the vial in a biohazard container.

If testing has not been started within 5 minutes a "Start Timeout" will occur indicating that the current cuvette must be discarded and a new cuvette placed in the instrument.

- Wait for a single beep signaling the conclusion of the test.
- Results are displayed as ACT seconds.
- Remove the cuvette from the instrument and dispose of in biohazard container.
- Record results of ACT quality control on the log sheet in each testing area.

Ranges are posted for the Normal and Abnormal control in each testing area. Contact the Point of Care pager if quality control does not come in range.

PATIENT TESTING:

1. Scan employee badge and scan cuvette barcode on the package, open pack and insert cuvette into the cuvette opening on the side of the instrument. The instrument will automatically identify the type of test cuvette inserted and initiate pre-warming.

2. During pre-warm stage, observe display for fault messages.

3. The instrument will signal ready with an audible tone, the display indicating the alternating messages **"ADD SAMPLE" and "PRESS START".** The instrument will remain in the ready mode for 5 minutes before a "Time Out Fault" will occur, requiring that a new cuvette be placed in the instrument. Discard cuvette and obtain a fresh cuvette.

4. Obtain blood sample. - (See Specimen Collection)

5. Fill the central circle of the cuvette well with freshly obtained whole blood. Add sufficient blood to the center sample well such that blood overflows into the outer well. This ensures that sufficient blood is available for sampling. Avoid generating bubbles in the sample well when applying the sample.

6. Depress the **START** key. Following an audible beep, a running time (in seconds) will be displayed. This indicates the test sequence has begun. Scan the patients MRN label.

NOTE: The instrument displays a fault if an inadequate sample has been provided.

7. An audible beep will signal the end of a test. Results are displayed. When performing an ACT+, the celite ACT equivalent time will be displayed. Record results.

RESULTS: Record in patients chart.

Reference ranges vary with patient care. Obtain a physician order if additional coagulation testing is needed.

PROCEDURE NOTES:

1. HEMOCHRON Elite 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 blood specimen, including the blood sample collection and the transfer of the blood to the test cuvette.

Tests may be affected by:

Foaming of the sample (air bubbles)
Hemolysis
Clotted or partially clotted blood
Unsuspected anticoagulation with either heparin or warfarin
Presence of a lupus anticoagulant

2. HEMOCHRON Elite test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any HEMOCHRON Elite test result exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests.

3. Whole Blood ACT-LR results less than 65 seconds will result in an “Out of Range-Lo” error message. Whole Blood ACT-LR results greater than 400 seconds will result in an “Out of Range-Hi” error message. The measuring range of the Hemochron Elite is 65-400 seconds.

4. All biohazard safety guidelines pertaining to the handling of human blood should be strictly adhered to when collecting, handling blood specimens and operating the HEMOCHRON Elite

CALCULATIONS:

There are no calculations in the Hemochron Elite ACT procedure.

MAINTENANCE / BATTERY

The HEMOCHRON Elite microcoagulation instrument can be operated by either utilizing the internal battery or by plugging the unit into the appropriate AC outlet using the supplied transformer. Since battery operation is most common, routine charging and discharging of the nickel-cadmium battery will improve its life span.

Coagulation tests can be performed on the HEMOCHRON Elite microcoagulation instrument while it is charging. A fully charged unit will provide approximately 2 hours of continuous test time.

NOTE: After removal of the instrument from the box, and prior to testing, an initial 8 hour battery charge period is required to completely charge the battery.

The transformer provided should be plugged into an appropriate outlet to charge the instrument when it is not in use to maintain the battery power level. To unplug the instrument from the transformer, firmly grasp the plug and pull.

DO NOT remove the plug from the instrument by pulling on the cord. Although the transformer can be left plugged into an AC outlet when the instrument is unplugged, it is recommended that the transformer be unplugged from the AC outlet when it is not being used to charge the batteries or run the instrument.
No routine maintenance is required.
Wipe down the Hemochron Elite with a bleach wipe or sani wipe to remove any residual dried blood.

Do not use any solvents or strong cleaning solutions as they may damage the instrument’s plastic

components.

GENERAL INFORMATION:

DO NOT use cuvettes past their expiration date or cuvettes that have been stored improperly. Only use Hemochron Elite cuvettes.

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 (see Service and Maintenance).

DO NOT use excessive force in depressing the START key.

DO NOT expose the HEMOCHRON Elite microcoagulation instrument to extremes in temperature above (37ºC). Such exposure could affect the performance of any type of electronic instrumentation.

INTERFERING SUBSTANCES:

The Hemochron Elite cuvette is cleared for the monitoring of heparin only.

The Hemochron Elite ACT-LR test uses Celite as the activator which is known to be artificially prolonged by aprotinin, a protease inhibitor. The ACT-LR is not intended for use with these patients.

REFERENCES:

1. HEMOCHRON. Whole Blood Anticoagulation System Operator's Manual

Donna Walck Point of Care Coordinator
Written By:

_____	_____
Lab Manager/Technical Supervisor	Date
_____	_____
Laboratory Medical Director	Date
_____	_____
Medical Director (Individual lab area)	Date

Annual Review: Medical Director/Designee Date

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Location of hard copy location(s): Core Lab Office_____

See Test Methods / Test Locations (POC.1.0002.0)

Date Archived: _____