Keywords: ACT-LR, activated clotting time, coagulation, hemochron, heparin, point of care

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Appendix B: ACT-LR IRC Direct Observation Checklist
Appendix C: ACT-LR PICU Direct Observation Checklist
Appendix D: ACT-LR CVIL Direct Observation Checklist
Appendix E: ACT-LR ENIS Direct Observation Checklist
Appendix F: Hemochron Signature Elite ACT-LR Competency Assessment
I. PURPOSE
This procedure provides instructions for performing ACT-LR testing on the HEMOCHRON Signature Elite. ACT-LR is used for monitoring patients receiving heparin anticoagulation therapy who attain a blood heparin concentration of up to 2.5 units of heparin/cc of blood.

II. ORDER
A physician’s order, standard protocol, or order by other health professional authorized to request laboratory test is required for ACT-LR.

III. SPECIMEN TYPE
A. Blood sample should not be collected until the instrument display indicates “Add Sample” and “Press Start.”
B. The cuvette requires a minimum volume of 15 microliters of fresh whole blood to perform the test, and will display “Sample too small” if insufficient sample is applied.
C. Samples with the following characteristics should be discarded immediately, and a fresh whole blood sample should be collected:
   1. Sample contamination with tissue thromboplastin
   2. Sample contamination with indwelling intravenous solutions
   3. Sample contamination with alcohol cleansing solution
   4. Samples with visible clotting or debris accumulation
D. Blood samples with any of the above conditions may interfere with the ACT LR.

IV. MATERIALS
<table>
<thead>
<tr>
<th>Reagents</th>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMOCHRON ACT-LR cuvettes</td>
<td>Latex –free gloves</td>
<td>HEMOCHRON Signature Elite Microcoagulation Instrument</td>
</tr>
<tr>
<td></td>
<td>JHMI approved biohazard waste container</td>
<td>AC/DC Power Module (ITC Part No. HX1025)</td>
</tr>
</tbody>
</table>

V. STORAGE REQUIREMENTS

<table>
<thead>
<tr>
<th>Hemochron Cuvettes</th>
<th>Temperature</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Refrigerated at 2-8 °C (36-46 °F)</td>
<td>Good until manufacturer’s expiration date</td>
</tr>
<tr>
<td></td>
<td>Room Temperature at 15-30 °C (59 -86 °F)</td>
<td>Good for 12 weeks</td>
</tr>
</tbody>
</table>

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1. Once a pouch is opened, the cuvette (stored in the folded pouch) is stable for only one day under refrigerated (2-8°C or 26-46°F) conditions.

2. Once a box of cuvettes is brought to room temperature, it is required that the box is labeled and re-dated with “Open Date” and new “Expiration Date”. Bring cuvettes to room temperature at least one hour prior to testing.

3. Do not use reagents past the manufacturer or the open expiration dates.

4. All reagents are stored in the POCT office. A working supply is maintained in each area of use.

VI. INTERFERING SUBSTANCES

The Hemochron Microcoagulation ACT-LR employs a Celite clot activator. Celite based assays are not for use with patients receiving aprotinin.

VII. SPECIMEN COLLECTION AND HANDLING

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

A. Syringe sample from an indwelling line
   1. Flush the sample port with an adequate amount of blood to free the line of contaminants. A typical heparin lock will require approximately 5.0 cc to clear the line. Greater volumes will be required to clear the longer lines.
   2. Obtain at least 0.2 cc of blood sample in a non-anticoagulated plastic syringe.
   3. Immediately dispense one drop of fresh whole blood into the sample well of the test cuvette, filling from the bottom of the well. This may be done either with or without a transfer needle. Sufficient quantity of blood must be added directly to the center of the sample well to fill to the top. Should a larger drop of blood extend above the top of the center sample well, push it over into the outer sample well.
   4. See “Patient Test Procedure” to perform the test.

B. Syringe sample from venipuncture
   1. Prepare the venipuncture site by cleansing with alcohol and allowing to air dry.
   2. Obtain a minimum of 0.2cc of blood in a non-anticoagulated plastic syringe.
   3. Immediately dispense one drop of fresh whole blood into the sample well of the test cuvette, filling from the bottom of the well. This may be done either with or without a transfer needle. Sufficient quantity of blood must be added directly to the center of the sample well to fill to the top. Should a larger drop of blood extend above the top of the center sample well, push it over into the outer sample well.
   4. See “Patient Test Procedure” to perform the test.

VIII. SAFETY PRECAUTIONS

1. Follow Standard Precautions and CDC handwashing guidelines when performing this test.

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

IX. QUALITY CONTROL

1. Internal Electronic Quality Control (EQC) should be run every 8 hours of patient testing.

2. Liquid Quality Control (LQC) should be run weekly. Refer to Quality Control procedure “Quality Control Procedure for Hemochron Signature Elite” POCTM008 for specific guidelines.

3. The Hemochron is configured to disallow patient testing when QC is due or failed.

4. QC results are transmitted to the POC middleware and are reviewed monthly by the POCT office.
X. PATIENT TEST PROCEDURE
Two unique identifiers should be available before testing. The operator will positively confirm the identity of the patient with two identifiers and use the medical record number as the Hemochron patient ID.

1. Insert cuvette.
2. Enter or confirm operator ID. Press Enter.
3. Screen will display “PID=______”.
4. Enter or confirm Patient ID.
5. “ID stored” will be displayed.
6. Instrument displays “Priming Pump…” and “… Warming…”
7. The instrument signals when ready with an audible tone, and screen will display the messages “Add Sample” and “Press Start”
8. Immediately add sample and then press start.
9. Once finished, meter beeps once and displays results.
10. Remove used cuvette and discard in biohazard container
11. Instrument is ready for next patient.
12. At the completion of patient testing the instrument will automatically shut down after being idle for 5 minutes. Alternate methods of shutting down are described in the Hemochron Signature Elite operator’s manual.

XI. CRITICAL ACTION VALUE
There is no Critical Action Value for ACT LR.

XII. REPORTABLE RANGE
Readable range for ACT-LR is 65-400 seconds. Out of range results will be reported as <65 or >400 respectively.

XIII. RESULTS INTERPRETATION
Test results should be scrutinized in light of a specific 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.

XIV. REFERENCES/INTERVENTIONAL RANGES

<table>
<thead>
<tr>
<th>Reference / Baseline Ranges</th>
<th>Interventional/ Therapeutic Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT-LR</td>
<td></td>
</tr>
<tr>
<td>CVIL/ CVC RR: 145 – 155 seconds</td>
<td>IIb/ IIIa patients: 225 – 250 seconds</td>
</tr>
<tr>
<td></td>
<td>Other patients: 250 – 300 seconds</td>
</tr>
<tr>
<td></td>
<td>Sheath pull: less than 180 seconds</td>
</tr>
<tr>
<td>CVIR/ Neuroradiology: 170 – 185 seconds</td>
<td>Sheath pull: less than or equal to 200 seconds</td>
</tr>
<tr>
<td>PICU</td>
<td>ECMO patients: 180 – 220 seconds</td>
</tr>
<tr>
<td></td>
<td>Renal patients: 110 – 182 seconds</td>
</tr>
</tbody>
</table>
XV. DOCUMENTATION/RESULT TRANSMISSION

Results are transmitted to the electronic medical record as follows:

- Connect the ethernet cable to the ethernet port on the meter and an active network jack.
- Press the “DATA BASE” button on the meter.
- Select option 6 “POCT>>NET”.

XVI. LIMITATIONS

A. Samples with hematocrits less than 20% or greater than 55% may exhibit an optical density outside the level of detection of the HEMOCHRON Signature Elite microcoagulation instruments.
B. Values exceeding 400 seconds are not reported on the HEMOCHRON Signature Elite microcoagulation instruments.
C. The 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.
D. Tests may be affected by any of the following conditions:
   1. Foaming of the sample (air bubbles)
   2. Hemolysis
   3. Clotted or partially clotted samples
   4. Unsuspected anticoagulation with either heparin or warfarin
   5. Presence of a lupus anticoagulant

XVII. PROCEDURAL NOTES

A. Do not use cuvettes past their expiration date or cuvettes that have been stored improperly.
B. 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.
C. Do not use excessive force in depressing the START key.
D. Do not drop the HEMOCHRON Signature Elite microcoagulation instrument.
E. Do not expose the HEMOCHRON Signature Elite microcoagulation instrument to extreme temperatures (above 37 °C or 98.6 °F). Such exposure could affect the performance of any type of electronic equipment.
F. The HEMOCHRON Signature Elite microcoagulation instruments are designed for use only with HEMOCHRON Signature Elite cuvettes. Test cuvettes must be properly stored according to the instructions in the package insert.
G. The HEMOCHRON. Signature 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 sample collection and the transfer of the blood to the test cuvette.
H. The transformer provided should be plugged into an appropriate outlet to charge the instrument when it is not in use to maintain battery power level.

XVIII. MAINTENANCE

A. Inspect and clean cuvette opening as required.
B. Remove residual dried blood or other foreign matter using moistened cotton swabs.
C. Remove any residual water with a dry cotton swab.
D. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a dilution of household bleach in water. Remove residual bleach with a water dampened cloth.
E. No other routine maintenance is required.
XIX. BATTERY CARE

The Hemochron Signature Elite can be operated on internal battery or plugged in to an AC outlet using the supplied transformer. It should be allowed to charge for a full 8 hours for adequate charge.

<table>
<thead>
<tr>
<th>Battery Warning</th>
<th>Meaning / Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHARGE BATTERY</td>
<td>Displayed intermittently when remaining power is insufficient to ensure test completion. Plug into AC power as soon as possible.</td>
</tr>
<tr>
<td>BATTERY FAULT</td>
<td>Battery is completely discharged. AC/DC power must be used for additional tests.</td>
</tr>
<tr>
<td>DISCONNECT AC ADAPTER IMMEDIATELY</td>
<td>AC/DC power module voltage is too high. Disconnect power to shut down instrument.</td>
</tr>
</tbody>
</table>

XX. INSTRUMENT DOWNTIME

When a particular Hemochron Signature Elite cannot be used for patient testing due to QC failure or mechanical or electronic instrument failure, document problems and attempted corrective actions in the “Comment” section of the QC logsheet. If problems cannot be resolved by the operator, contact the Point-of-Care Testing Program office at 5-2645, Meyer B1, Room 193.

XXI. PROFICIENCY TESTING

Proficiency Testing will be performed three times a year using whole blood samples obtained from an outside CLIA approved proficiency survey program such as the College of American Pathologists (CAP). Proficiency samples are run on one meter only. See Proficiency Testing procedure “Proficiency Testing Handling, Performance and Documentation” GEN001 for specific guidelines.

XXII. OPERATOR TRAINING

Initial training will include the following:

- Successful performance of Liquid Quality Control
- Completion of the initial training checklist
- Passing score on the initial training written quiz

Additional competency assessment is required 6 months after initial training.
XXIII. OPERATOR COMPETENCY
Training records will be kept in the employee’s personnel file. The POCT office will keep a copy of the training and competency records. Each operator's competency will be assessed annually in the following areas:

A. Routine patient test performance
B. Proper recording and reporting of test results
C. QC, proficiency testing, and maintenance performance
D. Instrument function checks and calibration performance
E. Test performance assessment (correlations and proficiency samples)
F. Assessment of problem-solving skills

XXIV. RELATED DOCUMENTS
A. POCTM008 Quality Control Procedure for Hemochron Signature Elite.
B. GEN001 Proficiency Testing Handling, Performance and Documentation

XXV. REFERENCES
1. HEMOCHRON® Whole Blood Microcoagulation Systems Activated Clotting Time (ACT-LR) CLSI Formatted Procedure
2. HEMOCHRON® Jr. Whole Blood Microcoagulation Systems Activated Clotting Time Plus (ACT-LR) Package Insert, 2/06
3. HEMOCHRON Signature Elite Whole Blood Microcoagulation System Operator’s Manual, 05/05
4. Procedure for HEMOCHRON® Jr. Signature Plus Activated Clotting Time (ACT-LR) Test(Category I)

XXVI. SPONSOR AND DEVELOPER
Sponsor:
Pathology Performance Improvement

Developer:
Point of Care Testing Office

Review Cycle: One (2) year

XXVII. SIGNATURES

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<th>Electronic Signature(s)</th>
<th>Date</th>
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</thead>
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<tr>
<td>William Clarke Medical Director of Point of Care Testing</td>
<td>10/26/2023</td>
</tr>
<tr>
<td>Aaron Tobian CLIA Laboratory Director, Johns Hopkins Hospital</td>
<td>10/24/2023</td>
</tr>
</tbody>
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