Procedure

Activated Clotting Time Low Range Testing (ACT-LR)

HEMOCHRON® Signature+

HEMOCHRON Signature Elite®

Approved by ______________________ Date __________________

Created by ______________________ Date __________________

Reviewed by ______________________ Date __________________

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Contact Person ______________________

Contact Number(s) ______________________
**Purpose**

The HEMOCHRON® Jr. Low Range Activated Clotting Time (ACT-LR) is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The ACT-LR assay demonstrates a 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). The ACT-LR test is for in vitro diagnostic use and is for use with any model HEMOCHRON Whole Blood Microcoagulation System.

**Principle**

HEMOCHRON Microcoagulation Systems utilize 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 (µL) 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 and thus facilitate accurate clinical test result interpretation.

**Safety**

Universal precautions should be observed through all phases of the testing procedure. Refer to the current version CLSI Document – Refer to current versions of: CLSI Document M29, Protection Of Laboratory Workers From Occupationally Acquired Infections and CLSI Document GP17, Clinical Laboratory Safety.
Specimen

A. Patient Preparation

There is no Patient preparation needed prior to testing.

B. Sample Collection

The HEMOCHRON Jr. ACT-LR is performed using fresh whole blood collected with a syringe from the patient. Refer to the most recent version of CLSI Document H21: Collection, Transport, And Processing Of Blood Specimens For Testing Plasma-Based Coagulation Assays, And Molecular Hemostasis Assays, that outlines the collection of specimens for coagulation testing.

When sampling through indwelling blood lines, flush access port thoroughly following institutional procedures. **A typical heparin lock will require approximately 5.0 cc to clear the line.**

Collection Procedure

1. Identify patient as directed by policy.

2. Collect a blood sample from the patient by venipuncture or an indwelling catheter line. **Obtain a minimum of 0.2 cc of blood in a non-anticoagulated plastic syringe.**

3. If using a syringe with needle:
   a. Use a 23 or larger gauge needle.
   b. Safely remove needle and discard according to hospital policy.

4. After dispensing the sample, discard syringe and transfer needle in accordance with institutional policy.

C. Sample Storage

Specimens must be processed immediately. There is no storage prior to testing.

D. Unacceptable Sample Types

Samples with any of the following characteristics should be discarded immediately, and a fresh whole blood sample must be collected prior to performing any test on any model HEMOCHRON Jr. instrument.

- Citrated tube used for collection.
- Sample collected into a pre-heparinized syringe.
- 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.

Equipment/ Materials/Reagents

A. Equipment

• HEMOCHRON Signature+ or Signature Elite Instruments.
• AC/DC Power Module (for use when charging the device):
  o 9 volt supplied with Signature+ instrument
  o 12 volt supplied with Signature Elite instrument.

B. Materials

• Fresh whole blood sample-collected in a plastic, non-heparinized syringe
• Optional as disposal will be directed by each site:
  o Biohazard Disposal Receptacle
  o Sharps Disposal Receptacle

C. Reagents

HEMOCHRON Jr. ACT-LR test cuvette containing a dried preparation of Celite, stabilizers, and buffers and are available from ITC.

• Catalog number: JACT-LR

Each ACT-LR cuvette is individually packaged in a foil pouch with a desiccant. Each box contains 45 individually pouched cuvettes. Cuvette pouches are stamped with a lot-specific expiration date.

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

D. Reagent Preparation

HEMOCHRON Jr. ACT-LR test cuvettes must be at room temperature before opening the pouch.

E. Reagent Storage Requirements

• While refrigerated (2 - 8°C), the unopened foil-pouched ACT-LR 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 twelve weeks.
- 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.
- Re-dating must never exceed the marked expiration date.
- Once a pouch is opened, the cuvette (stored in the folded pouch refrigerated) is stable for 7 days.
- HEMOCHRON Jr. ACT-LR cuvettes should not be exposed to temperatures in excess of 37°C.

Quality Control

Routine Quality Control (QC) testing and tracking should be a part of a comprehensive Quality Assurance (QA) program.

The manufacturer’s Quality Control protocols for HEMOCHRON Signature+ and HEMOCHRON Signature Elite systems are described below. Each institution must follow the manufacturer’s recommendation at a minimum, and may need additional protocols as specified by the accrediting authorities for compliance.

A. Calibration

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

B. System Self-Checks

All models of HEMOCHRON instruments perform a “Self-Check” every time they are activated and a test is performed. When a test is initiated by inserting a cuvette, system checks are automatically performed and include:

- 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 tests are functioning properly.
- Verification that the cuvette temperature is warmed to 37°C ± 1°C. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.

After the sample is added and the “Start” key is pressed, the system continues a self-checking process:
• Verification that the sample is present and is of sufficient size to run the test. This ensures 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 is displayed.

• 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.

C. Electronic Quality Control (EQC) for Signature+ System

Both Normal (30 ± 5 ACT seconds) and Abnormal (300 ± 10 ACT seconds) Electronic System Verification Cartridges (EQC) are used to provide a check of the instrument for daily EQC. The EQC Cartridges are recommended for use every eight (8) hours of operation.

Use of Electronic System Verification Cartridges for EQC

1. Insert an EQC cartridge into the cuvette slot.
2. The instrument will beep once and display “EQC...TEST.”
3. System verification checks are performed during this process.
   a. If a fault is encountered, the instrument will beep several times and display the error message.
   b. Refer to the Troubleshooting section of the Operators Manual to resolve an error message.
4. The message “Press EQC” and “Start Now” will then appear alternately on the display.
5. Press” START” button on the cartridge, do not press the instrument “Start” key:
   a. The EQC cartridge will simulate an endpoint.
   b. The result will be displayed in seconds.
6. The endpoint should be within the acceptable range shown on the EQC cartridge when compared.
7. Record results as required by institutional policy.

Optional: Temperature Verification Cartridge for Temperature QC (TQC)

A Quality Control temperature evaluation of the HEMOCHRON Jr. Signature+ instrument is performed automatically each time a test is run. Any errors found in the temperature control system of the instrument will also be displayed on the LCD screen.

An optional Temperature Verification Cartridge can be obtained from ITC to verify that the Signature + instrument is maintaining the proper temperature of 37° ± 1.0° C.
1. Insert the TQC cartridge into the HEMOCHRON Signature+ instrument. The instrument will beep and alternately display: “Test…TQC”, and “Warming.”

2. When the TQC cartridge temperature of 37° ± 1°C is detected, the instrument will beep and alternately display: “Remove TQC”, and “Read TQC Temp.”

3. Remove the TQC cartridge and read the displayed temperature on the cartridge immediately. The acceptable reading is between 36.0°C and 38.0°C.

4. Record results as required by institutional policy.

**Note:** If the temperature reading is out of range, discontinue use of the instrument and contact ITC Technical Support.
- Call toll-free in the US: 800-631-5945
- If calling from outside the US: 001-732-548-5700
- E-mail: www.techsupport@itcmed.com

**D. Electronic Quality Control (EQC) for Signature Elite System**

EQC can be used to provide a two-level electronic verification of instrument performance. This testing does not use any external device. The time interval to perform EQC is recommended by the manufacturer to occur every eight (8) hours of each patient-testing day.

EQC will check a Normal level (30 seconds), and an Abnormal level of QC (300 seconds or 500 seconds) plus the internal temperature, and will store each result. If one test fails to meet specifications, the EQC test will stop and record all results as failed. If the user aborts the EQC, the test is not saved to the database or printed. If a cuvette is inserted in the instrument, EQC will be aborted and recorded as a failed test.

EQC can be programmed to be performed automatically at prescribed intervals by the instrument through the Configuration Manager or can be performed manually by the Operator.

**Manual Performance of EQC**

1. Display the QC status menu by pressing the “QC” key before a cuvette is inserted.

2. Press “1-EQC”. The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing.

3. When the test is completed, the results are displayed on the screen and written to the QC database.

**Automatic Performance of EQC**

1. If enabled by designating in the Configuration Manager programming, EQC tests will be performed automatically at preset intervals if the Elite instrument is “On” and connected to a DC source by the transformer.

2. If the instrument is not in use, the EQC will automatically initiate when the instrument is activated.
NOTE: If the electronic QC procedure yields an on-screen ERROR message discontinue use of the instrument and contact ITC Technical Support
  - Call toll free in the US: 800-631-5945
  - Outside the U.S: 001-732-548-5700
  - E-mail at: techsupport@itcmed.com

E. Liquid Quality Control of Test Cuvettes (LQC)

The manufacturer makes recommendations for the minimum LQC frequency. Accrediting agencies may have requirements that specify an increased frequency.

1. Frequency of LQC - Each lot of the HEMOCHRON Jr. cuvettes should be validated for performance using 2 levels of LQC:
   - When a new shipment is received, AND
   - Once per 30 calendar days thereafter.

2. Liquid QC Material

   Each box of directCHECK® Whole Blood Quality Control contains fifteen (15) dropper vials and each vial contains dried whole blood (0.5 mL) and diluent (0.7 mL). There are also four (4) re-usable protective sleeves for use in processing the control material.

   Complete instructions and acceptable performance ranges are included on each package insert.

   - directCHECK Whole Blood Quality Control product is available through ITC:

     Catalog numbers:
     - Level 1 – DCJLR-N
     - Level 2 – DCJLR-A

F. Procedure for Performing LQC Tests

1. Remove the directCHECK vials, one each Level 1 and Level 2, from the refrigerator and allow them to come to room temperature prior to testing.

2. Remove two ACT-LR cuvettes from the refrigerator and allow them to come to room temperature. The foil pouch must be at room temperature before opening.

3. Visually inspect each vial to insure that the glass ampule inside the plastic vial is intact.

4. Press “QC” soft key and select QC level (1-Normal" or 2-Abnormal") to tag the sample.

5. After the reagents have reached room temperature, open the cuvette pouch and insert into the cuvette slot on the side of the instrument.
6. The instrument will signal when ready with an audible beep, and display alternating messages: “Add Sample” and “Press Start”.
   a. The instrument will remain in the ready mode for five (5) minutes.
   b. If the testing has not been started within five (5) minutes, a “Start timeout” will occur indicating that the current cuvette must be discarded and a new cuvette placed in the instrument.

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

8. Insert the directCHECK vial into the white protective sleeve.

9. Holding the vial upright, tap the directCHECK vial on the table top to settle the inner glass ampule to the bottom of the plastic vial.

10. Crush the inner glass ampule by bending the vial over the edge of a table top.

11. Immediately repeat this crushing action one to two more times at different locations of the vial to ensure complete breakage of the glass ampoule.

12. Quickly invert the dropper vial (dropper tip down) end-to-end 10 times and use a downward snapping motion of the wrist to ensure the control material flows to dropper tip.

13. Remove and retain the vial cap.

14. Squeeze the vial to discard the first drop of control material into the vial cap.

15. Immediately dispense as many drops of control material as needed to fill the cuvette sample well flush to the top. Should a large dome extend over the top of the center sample well, push it over into the outer sample well.

16. Press the “START” key.

17. Dispose of the vial and vial cap according to institutional policy and retain the protective sleeve for reuse.

18. Wait for a single beep signaling the conclusion of the test.

19. Results are displayed as ACT Celite-equivalent seconds.

20. Record results according to Institutional policy.

21. Compare the ACT test result with the acceptable range for each level of QC as published in the package insert included in each box. These ranges are Lot number-specific so there is a slight variation from lot to lot.

22. Remove the cuvette from the instrument and dispose according to institutional policy.
G. Out-of-Range LQC Recommendations

1. In cases where LQC results are outside of an acceptable range, the cause may be one of the following categories:
   - Improper Test or Mixing Technique
   - Expired or improperly stored QC Material
   - Expired or improperly stored Test Cuvettes
   - Instrument temperature.

2. If none of the above parameters are suspect, repeat the test using LQC material with the same lot number.

3. If this repeat does not fall within the expected range, address the above parameters again.

4. Obtain a cuvette from a different lot number and repeat the test using LQC of the same lot number.

5. If this repeat test still does not fall within the expected range: Obtain the backup Hemochron Signature Elite, assure that the liquid controls have been successfully run within the previous 30 days before performing any patient testing.

6. Notify clinical engineering and the POCT staff at 686-7044, 686-7066 or 526-4464 about the malfunctioning meter

7. The instrument or the cuvettes cannot be used until QC values obtained are within range.

ITC Technical Support must be contacted prior to sending an instrument for service.
   o Toll-free in the US: 800-631-5945
   o Outside the US: 001-732-548-5700
   o E-mail: techsupport@itcmed.com

Patient Testing

A. Patient ID (PID) and/or Operator ID (OID) Using the Signature+ Instrument

This feature must be programmed into the instrument with Configuration Manager for use.

   - For the PID or OID: up to nine digits other than zero (0) can be entered.
   - If a Valid OID is required, the instrument will only accept an OID matching one pre-entered into the instrument database.
B. Patient ID (PID) and/or Operator ID (OID) Using the Signature Elite Instrument

The PID and OID can be read from a barcode label using the internal barcode scanner, or can be entered using the keypad. This feature must be programmed into the instrument with Configuration Manager for use.

- When prompted for OID, the operator has the option to either scan the operator’s barcode or **scan or** manually enter their OID using the touchpad up to 16 alphanumeric characters. This function is dependent upon the options selected in **Configuration Manager**.

- When prompted, the operator can either scan the patient’s barcode or enter the PID manually using the touchpad up to 20 alphanumeric characters. This function is dependent upon the options selected in **Configuration Manager**.

- If the “Valid OID” function has been activated, only OIDs that have been previously programmed into the system will be accepted as operators.

C. Test Procedure for Signature+ Instruments and Signature Elite Instruments

1. Remove test cuvette pouch from the refrigerator and allow it to reach room temperature.

2. Open test cuvette pouch only at room temperature and remove cuvette.

3. Insert the cuvette into the cuvette opening.

4. The instrument will identify the test cuvette inserted and display the test.

5. This initiates the pre-warm/self-check mode.

6. During pre-warm stage, observe the display for any fault messages.

7. The instrument will signal when “Ready” with an audible tone.

8. The screen will display the messages “Add Sample” and “Press Start.”

   a. The instrument will remain in the ready mode for five (5) minutes.

   b. If the testing has not been started within five (5) minutes, a “Start timeout” will occur.

   c. Discard cuvette and obtain a fresh cuvette.

9. Obtain a fresh whole blood sample as previously outlined in this procedure.

10. Immediately dispense one large drop of blood into the sample well of the test cuvette.

11. Fill the sample well from the bottom up with fresh whole blood.

12. A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top.
13. Should a large drop of blood extend above the top of the center sample well, creating a “dome-like” appearance, push it over into the outer ring with the tip of the dispensing device.

14. When transferring blood into the sample well, do not force blood into the pin located on the center of the sample well.

14. Avoid generating air bubbles in the sample well when applying the sample.

15. Press the “START” key.

16. Test completion will be indicated by a single beep.

17. Record results as directed by Hospital policy.

18. Remove the cuvette from the instrument and dispose in accordance with institutional policy.

Results

A. Expected Results-Normal Ranges

The Hemochron ACT+ was evaluated using fresh whole blood from normal volunteer donors (n=20) and hospitalized patients not receiving heparin treatment (n=100), the results are shown Celite equivalent Hemochron ACT values.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal donors</td>
<td>20</td>
<td>103 sec.</td>
<td>11 sec.</td>
<td>81-125</td>
</tr>
<tr>
<td>Patients</td>
<td>100</td>
<td>124 sec.</td>
<td>14 sec.</td>
<td>96-152</td>
</tr>
</tbody>
</table>

B. Reporting Results

Upon test completion, report all test results in seconds to physician and document with date, time, ACT result, patient ID, and operator id in anesthesia record.

C. Procedures for Abnormal Results

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 ACT results greater than 400 seconds are not reported on the instrument. Instead, an “Out of range – Hi” message will be displayed.

Celite-equivalent ACT results that exceed 400 seconds may indicate an extremely high sensitivity to heparin by the patient, so may 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.
D. Calculations

There are no extraneous calculations associated with this test.

E. Result Review

All results to include all Quality Control and Patient testing should be reviewed as directed by policy at each site.

Proficiency Testing (PT)

Regulatory agencies will direct the participation in a PT program.

Receiving, distribution, handling and preparing of the PT material, and reporting results will be directed by the institutional policy.

Under no circumstances will any PT samples be referred to another facility for testing or confirmation of the results.

Notify the issuing agency if there is a delay in receipt or damage to the testing material.

Procedural Notes

A. AC/DC Power Module Recommendations

- The power module 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 power module, firmly grasp the plug and pull.

- Do not remove the plug from the instrument by pulling on the cord.

- Although the power module can be left plugged into an AC outlet when the instrument is unplugged, it is recommended that the power module be unplugged from the AC outlet when it is not being used to charge the batteries or run the instrument.

B. General Information

- Do not use cuvettes past their expiration date or cuvettes that have been stored improperly.

- 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.
• Do not use excessive force in pressing the “START” key.

• Do not allow the HEMOCHRON Microcoagulation instruments to hit any hard surfaces or fall.

• Do not expose the HEMOCHRON Microcoagulation instruments to temperatures extremes: below 15° C or above 37° C. Such exposure may affect the performance of the instrument.

• The instruments are designed for use only with HEMOCHRON Jr. cuvettes. The cuvettes must be properly stored according to the instructions in the appropriate HEMOCHRON Jr. cuvette package insert.

• Test results may be affected by poor technique during blood collection and delivery to the sample well.

Limitations

As with all diagnostic tests, 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. Samples with a hematocrit of less than 20% or greater than 55% are not recommended due to optical densities outside of the instrument levels of detection.

A. 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 Weight Heparins (LMWH).

B. Interfering Substances

The HEMOCHRON Jr. ACT-LR cuvette is cleared for the monitoring of heparin only.

The HEMOCHRON Jr. 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.

Maintenance

A. Routine Maintenance of the Instrument

• Inspect and clean the cuvette opening as required.

• 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.

• 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.

B. Service

The HEMOCHRON Microcoagulation instruments are almost completely self-monitoring by automatically checking internal circuitry and reporting problems on the display screen. Malfunctions are indicated by fault messages detailed in the section on TROUBLESHOOTING in the appropriate HEMOCHRON Microcoagulation System Operator’s Manual.

C. Battery Care

HEMOCHRON instruments can be operated either on internal battery or plugged into an AC outlet using the supplied power module. Signature+ instruments must be allowed to charge for a full 16 hours prior to using the instrument for the first time for best performance. Signature Elite instruments should be allowed to charge for a full 8 hours prior to using the instrument for the first time.

A fully charged battery will operate for approximately 17 average test cycles greater than 500 seconds per test, or 49 average test cycles at 150 seconds per test. The operating time for a fully charged battery is 2-3 hours (minimum), and the battery life is 500 recharges.

The “Battery is Low” message will appear on the display screen at the beginning of a test to alert the user if the battery is running low. At this point, the instrument has approximately ten minutes of battery time remaining to perform coagulation testing. Once this message appears, plug the instrument as soon as possible.

When the batteries are drained to the point that valid testing may not be performed, the message “CHARGE BATTERY” is displayed intermittently. At this point, the instrument must be plugged into the power module and an AC source for operation and recharging. Once plugged into an AC outlet, the instrument can be utilized, and testing resumed.

D. Instrument Downtime

During instrument downtime, patient samples will be run on alternate instruments as designated by the institution.

Operator Certification

Documentation of certification will be available in the employee file and/or training tracker or in training records when training was performed by POCT staff.
References


CLSI H03 Document Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard.

CLSI Document GP2 Laboratory Document Development and Control: Approved Guideline

CLSI M29 Document Protection of Laboratory Workers from Occupationally Acquired Infections Guideline
CLSI Document GP17 *Clinical Laboratory Safety for information on laboratory safety and special requirements.*

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