Procedure Title:	Activated Clotting Time: Hemochron Signature Elite ACT-LR		
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Activated Clotting Time
Hemochron Signature Elite
ACT-LR

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.

SPECIMEN REQUIREMENTS:

Patient Preparation:

- There is no Patient preparation needed prior to testing.

Specimen Type and Collection Method:

- The Hemochron Jr. ACT-LR is performed using fresh whole blood collected with a syringe from the patient.
- When sampling through indwelling blood lines, flush access port thoroughly following FHN procedures.

Collecting Specimen:

1. Identify patient using first and last name and date of birth.
2. Collect a blood sample from the patient by venipuncture or an indwelling catheter line.
3. If using a syringe with needle:
    a. Use a 23 or larger gauge needle.
    b. Safely remove needle and discard in sharps container.
4. After dispensing the sample, discard syringe in biohazard container.

Special Handling or Storage Conditions:

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

Criteria for Specimen Rejection:

- 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 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, REAGENTS, AND SUPPLIES:

Equipment or Instrumentation:

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

Reagents or Media:

- Hemochron Jr. ACT-LR test cuvette containing a dried preparation of Celite, stabilizers, and buffers. 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.

Reagent Preparation:

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

Reagent Performance Parameters:

- The Analytic Measurement Range (AMR) for this method is 65-400 seconds.

Storage Requirements:

- While refrigerated (2 to 8°C), the unopened foil-pouched ACT-LR cuvette is stable until the marked expiration date.
- Room temperature storage (15 to 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 available for the cuvettes and should be completed and placed on each cuvette that has been stored at room temperature.
  - 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 seven days.
- Hemochron Jr. ACT-LR cuvettes should not be exposed to temperatures in excess of 37°C.

CALIBRATION:

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

INSTRUMENT MAINTENANCE:

- 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.
- Document maintenance performed on the Hemochron Signature Elite Maintenance Log

QUALITY CONTROL:

- The Hemochron Signature Elite performs a "Self-Check" every time it is 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.

QC Material:

- *direct*CHECK Whole Blood Quality Control
    - Level 1 – DCJLR-N
    - Level 2 – DCJLR-A

Frequency of Performance:

- Electronic Quality Control (EQC):
    - Every 8 hours of patient testing
- Liquid Quality Control (LQC):
    - Every 8 hours of patient testing

- With each new lot of cuvettes
- Every 30 days

Procedure:

Electronic Quality Control (EQC):

The Internal 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. If a cuvette is inserted in the instrument, EQC will be aborted and recorded as a failed test.

1. Electronic Quality Control (EQC) tests will be performed automatically at 8 hour 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 the Point of Care Coordinator.

Liquid Quality Control (LQC):

1. Remove the *direct*CHECK 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. After the reagents have reached room temperature, open the cuvette pouch and insert into the cuvette slot on the side of the instrument.

5. Scan the barcode on the cuvette package when prompted. "Lot Stored" will be displayed.

6. Scan or manually enter your operator ID when prompted. "Stored" will be displayed.

    a. If manually entering your operator ID, you will need to press and hold the "Enter" button until "Stored" is displayed.

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

8. Scan the barcode on the LQC insert when prompted. "Lot Stored" will be displayed.

9. 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.

10. Remove the top of the plastic seal from the *direct*CHECK vial.

11. Insert the *direct*CHECK vial into the white protective sleeve.

12. Holding the vial upright, tap the *direct*CHECK vial on the table top to settle the inner glass ampule

to the bottom of the plastic vial.

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

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

15. 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.

16. Remove and retain the vial cap.

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

18. 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.

19. Press the "START" key.

20. Dispose of the vial and vial cap in biohazard and retain the protective sleeve for reuse.

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

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

23. Record results as "Pass" or "Fail" on the QC log sheet.

24. Remove the cuvette from the instrument and dispose in biohazard.

Acceptable Limits:

- Acceptable performance ranges are included on each package insert.

Corrective Action:

- 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.
- If none of the above parameters are suspect, repeat the test using LQC material with the same lot number.
- If this repeat does not fall within the expected range, address the above parameters again.
- Obtain a cuvette from a different lot number and repeat the test using LQC of the same lot number.
- If this repeat test still does not fall within the expected range, contact the Point of Care Coordinator.
- The instrument or the cuvettes cannot be used until LQC values obtained are within range.

Recording QC Data:

- Record results on the QC log as either "Pass" or "Fail"
- Values will be stored on the instrument and printed monthly.

PROCEDURE:

1. Remove a cuvette from the refrigerator and allow to reach room temperature, if none are already available.
2. Insert the cuvette into the cuvette opening.
3. The instrument will identify the test cuvette inserted and display the cuvette lot list.
4. Scan the barcode on the cuvette wrapper. "Lot Stored" will be displayed.
5. Scan or manually enter your operator ID.
    a. If manually entering your operator ID, you will need to press and hold the "Enter" button until "Stored" is displayed.
6. Scan or manually enter the patient ID.
    a. If manually entering the patient ID, you will need to press and hold the "Enter" button until "Stored" is displayed.
7. A pre-warm/self-check mode is performed during this time.
8. During pre-warm stage, observe the display for any fault messages.
9. The instrument will signal when "Ready" with an audible tone.
10. 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.
11. Obtain a fresh whole blood sample as previously outlined in this procedure.
12. Immediately dispense one large drop of blood into the sample well of the test cuvette.
13. Fill the sample well from the bottom up with fresh whole blood.
14. A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top.
15. 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.
16. When transferring blood into the sample well, do not force blood into the pin located on the center of the sample well.
17. Avoid generating air bubbles in the sample well when applying the sample.
18. Press the "START" key.
19. Test completion will be indicated by a single beep.
20. Record results in patient record.
21. Remove the cuvette from the instrument and dispose in biohazard.

REPORTING RESULTS:

Reference Intervals:

- Non-heparinized patients: 89-169 seconds
- Removal of sheath: < 180 seconds

Reporting 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.

Reporting Format:

- Results displayed as "Out of Range- Lo" should be recorded as < 65 seconds
- Results displayed as "Out of Range – Hi" should be recorded as > 400 seconds

Result Entry:

- Patient results will be recorded in the patient's record.
- The two staff member's names who verified the result will also be recorded with the result.

LIMITATIONS OF PROCEDURE:

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

Interfering substances

- The Hemochron Jr. 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.

PROFICIENCY TESTING:

- Proficiency testing will be rotated amongst all staff performing testing.

COMPETENCY REQUIREMENTS:

- Staff will be evaluated at initial training, 6 months after initial training, and then annually thereafter.

PROCEDURE NOTES:

- 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.
- 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.

REFERENCES:

Hemochron Signature Elite Whole Blood Microcoagulation Operator's Manual. 12/2019
Hemochron Jr. whole Blood Microcoagulation Systems Low Range Activate Clotting Time (ACT-LR) Package Insert 1/16/2019