OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE

NUMBER: 11722
VERSION: 2

SUBJECT/TITLE: POCT -15-01 ACT TEST BY HEMOCHRON SIGNATURE ELITE

POLICY: **ACT – Activated Clotting Time**

PURPOSE: Activated Clotting Time test is one of the general coagulation screening tests used to measure the functionality of the blood coagulation cascade. The ACT-LR demonstrates linear correlation to the anticoagulation effects of heparin up to 2.5 units/ml of blood. It is intended for use in monitoring low to moderate heparin doses frequently associated with procedures such as cardiac catherization, Extracorporeal Membrane Oxygenation (ECMO), hemodialysis, and Percutaneous Transluminal Coronary Angioplasty.
Close monitoring and control of anticoagulation is desirable to ensure clot free blood flow while minimizing bleeding complications following the procedure.

DEPARTMENTS: **PATHOLOGY & LABORATORY SERVICES**

DEFINITIONS: The Hemochron® Signature Elite Microcoagulation Systems utilize a mechanical endpoint clotting mechanism in which testing occurs within the disposable cuvette. Following whole blood sample introduction, the instrument precisely measures 15 microliters of blood and automatically moves it into the test channel within the cuvette. The remainder of the blood 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 a series of LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves between the detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The instrument recognizes that the clot endpoint has been achieved when the movement decreases below a predetermined rate. The instruments report the Celite equivalent ACT value in seconds.

PROCEDURE: **TEST UTILIZATION:**

The Activated Clotting Time test first described by Hattersley in 1966, is the method of choice for monitoring heparin therapy during interventional procedures such as PTCA. While heparin therapy is essential in maintaining hemostasis during the procedure, its administration can pose significant risk to the patient. Patients can vary as much as twelve fold in heparin sensitivity. Overdosing heparin can result in dangerous bleeding, whereas underdosing heparin can lead to

thrombosis. Therefore, monitoring heparin therapy is vital in guarding against these undesirable side effects.

The ACT-LR test result is automatically converted to a reference Celite ACT value. Upon test completion, the instrument's digital timer will display only the Celite equivalent ACT value in seconds. Display of this Celite equivalent value improves the ease of test result interpretation.

TEST PERFORMANCE AND SUPERVISION:

The Hemochron® Signature Elite Activated Clotting Time testing may be performed by Olive View-UCLA Medical Center personnel at Cardiac Catherization Lab including physicians, Registered Nurses, Nurse Practitioners, Clinical Laboratory Scientists and other staff members who satisfy California State Department of Health Services and CLIA requirements for testing personnel and have been trained and authorized to do such testing under the Olive View-UCLA Medical Center Point of Care Testing Program. Supervision of testing personnel is the responsibility of the testing site section managers, i.e. Nursing, Clinical Laboratory, etc.

SPECIMEN:

Patient Preparation:
Blood samples must not be collected until the instrument display indicates **ADD SAMPLE and PRESS START.**

Type:
The Hemochron® Signature Elite ACT is optimally performed using 0.05mL of fresh whole blood. The cuvette requires a minimum volume of 15µl to perform the analysis, and will display a "Sample Too Small" if insufficient sample is applied.

Collection Procedure:
Blood samples to be used for coagulation testing must be collected according to the following procedures to assure the integrity of the fresh whole blood sample. Do not collect fresh whole blood samples using glass blood collection tubes. Do not obtain blood from heparinized access line, lock or indwelling heparin lock. When sampling through indwelling blood lines, flush access port thoroughly.

1. Verify that the instrument has enough power to perform the test by visually checking the battery charge status indicator on the upper right hand corner of the instrument. Attach instrument to AC adapter if needed.
2. Insert the cuvette into the cuvette opening on the right side of the instrument.
3. During instrument warming, obtain 0.2 mL of blood with the syringe.
4. Immediately dispense one drop of blood into the sample well of the test cuvette, filling from the bottom of the well up. This may be done either with or without a transfer needle. 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.

5. Depress the START key.

EQUIPMENT AND MATERIALS:

The Hemochron® Jr.ACT-LR 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. Each box of ACT-LR test cuvette contains 45 pouches, each containing one Hemochron Jr. ACT-LR test cuvette and on desiccant. Cuvette pouches are stamped with a lot specific expiration date.

CAUTION: All used test cuvettes should be considered as potentially infectious, handled with care and disposed of using standard medical waste disposal policy.

Equipment:
1. Hemochron® Signature Elite Whole Blood Microcoagulation Systems
2. AC/DC Power Module
3. AC Power Cord

Materials:
1. Preloaded Hemochron® Jr. ACT-LR test cuvettes
2. directCheck® Whole Blood Control ACT-LR, Level 1 and Level 2
3. 1 mL or 3 mL plastic syringes with 23 or 21 gauge needle
4. Bleach wipes

Reagent Preparation:
No reagent preparation required.

Reagent Storage Requirements:

Hemochron® Jr. Test Cuvettes:
1. When refrigerated (2 – 8°C), the foil-pouched PT cuvette is stable until the manufacturer's expiration date.
2. Room temperature storage is (15 - 30°C) is optional for sealed-pouched cuvettes.
3. **Room temperature re-dating is to a maximum of 12 weeks**, but must never exceed the marked expiration date. A re-dating label is included on the side panel of each box of cuvettes and should be completed.
4. **Once a pouch is opened, the cuvette (stored in the folded pouch) is stable for seven days under refrigerated (2 - 8°C) conditions**.
5. Hemochron® Jr. test cuvettes should not be exposed to temperatures in excess of 37°C.

directCheck® Normal and Abnormal Controls:

1. When refrigerated (2 – 8°C), the vials are stable until the marked expiration date.
2. The Quality Control products should never be exposed to temperatures in excess of 37°C.
3. Reconstituted vials should be used immediately.
4. **directCheck® Quality Control products may also be stored at room temperature for up to 4 weeks**. The marked expiration date must not be exceeded.
5. A re-dating label is provided and should be marked with 4 weeks dating if stored at room temperature.

QUALITY CONTROL:

Electronic Quality Control must be performed every 8 hours of operation. Internal EQC will check two levels of QC plus the temperature and store results.

directCheck® liquid controls are used to verify the performance of the Hemochron® Signature Elite Microcoagualation Systems.

- Performed on each lot of cuvettes or when a new shipment is received.
- Once a week with a valid IQCP in place.
- If the meter is dropped.
- When troubleshooting the system

Self Check:

The Hemochron Signature Elite instrument 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:

1. Verification of adequate battery power to complete a full test.
2. Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.
3. Verification that the cuvette temperature is warmed to 37°C ± 1.0°C. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.
4. Verification that a sample is present and is of sufficient size to run the test. This insures 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.
5. 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.

Verification Of Instrument Temperature:

Instrument temperature is **automatically** checked whenever EQC is carried out. The instrument temperature check verifies that a temperature of 37°C ± 1.0°C is maintained.

Note: If the temperature reading is out of range, please contract Accriva Diagnostics at 1-800-631-5945

Instrument Performance QC:

Automatic internal Electronic Quality Control (EQC) is used to provide a two-level electronic verification of instrument performance.

1. Press and hold the **START** button to turn on the instrument.
2. Press **QC** then **1** (Run EQC).
3. Enter/Scan your 6-digit employee number. Press ENTER until STORED appears on the screen.
4. The instrument will display **WARMING** and checks instrument temperature.
5. **TESTING IN PROGRESS** will display and starts with **Normal EQC**.
6. The machine will continue on with **Abnormal EQC**.
7. Once the tests are completed, **TEST COMPLETED**, **CANCEL TO EXIT** will be displayed.
8. The following results will be displayed on your screen:

EQC:	**Level 1** (Normal) = test result	Pass (if result is within range)
	Level 2 (Abnormal) – test result	Pass (if result is within range)
	Temperature = test result	Pass (if result is within range)
	EQC PASSED	

9. Press **CANCEL** to exit.

If one of the results fails, the test will stop and record all results as failed. If the user aborts the internal EQC test, the test will not be saved to the database.

Note: If the Electronic QC, Instrument Temperature and/or directCHECK® control results fall outside the expected range, the system is not functioning properly. DO NOT USE the system to test patient's POC ACT until the Electronic QC, Instrument Temperature and/or directCheck® control results fall within the expected range.

Procedure for Performing Liquid Quality Control (directCheck® Whole Blood Control):

1. Remove the directCheck® vials (Normal and Abnormal) from the refrigerator and allow them to come to room temperature prior to testing. This could take up to 60 minutes.
   Note: directCheck® vials (Normal and Abnormal) can be stored at room

temperature for up to 4 weeks.

2. Verify that the instrument has enough power to perform the test by visually checking the battery charge status indicator on the upper right hand corner of the instrument. Attach instrument to AC/DC power module into an electrical service outlet, if needed.
3. Insert the cuvette into the cuvette opening on the right side of the instrument.
4. At the prompt **ENTER OID**, enter/scan your employee ID#. Press **ENTER** and hold until **STORED**.
5. At the prompt **ENTER PID**, Press **QC**.
6. Under **QC SELECTS**, PRESS **1** (**QC NORMAL**). Verify screen display, **ACT LR QC NORMAL**.
7. During the pre-warm stage, observe the display for any fault/warning messages. The instrument will signal when ready with an audible beep, and display alternating messages, **ADD SAMPLE** and **PRESS START**.

Note: The instrument will remain in the ready mode for five minutes. At the end of five minutes, a START TIMEOUT will occur indicating that the current cuvette must be discarded and a new cuvette placed in the instrument.

8. Remove the top of the plastic seal from the directCheck® vial (Normal Control). Insert the directCheck® vial into the white protective sleeve.
9. Holding the vial upright, tap the directCheck® vial on the tabletop to settle the inner glass ampule to the bottom of the vial.
10. Crush the inner glass ampule by either bending the vial over the edge of a tabletop or by crushing the vial between two fingers. Immediately repeat this crushing action one to two more times.
11. Quickly invert the dropper vial end to end 10 times. Remove and retain the vial cap.
12. While inverting the vial (dropper tip down), use a downward snapping motion of the wrist to ensure the control material flows to dropper tip. Squeeze the vial to discard the first drop of control material into the vial cap.
13. Immediately dispense (within 30 seconds) 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.
14. Press the **START** key.
15. Wait for a single beep signaling the conclusion of the test. Results are displayed as the Celite equivalent clotting time.
    Screen will Display **TEST COMPLETED**, **QC PASSED.**
16. Record ACT result in log provided. Verify that the results are within the acceptable range for each level of quality control reagent as published on the back page of the package insert in each box of quality control material. (These ranges are Lot# specific and may vary slightly from lot to lot).
17. Proceed to graph the result on the Quality Control Chart.

18. Remove cuvette from the cuvette opening on the right side of the instrument.
19. Proceed with the Abnormal control. Follow steps 2-18, selecting **2** (**ABNORMAL CONTROL**) under **QC SELECTS**. Verify screen display, **ACT LR QC ABNORMAL**.
20. If result is outside the expected range, refer to "Out-of-range Quality Control Procedure".

Note: Notify POCT when new lot of controls are obtained, parallel testing needs to be performed. Comparison study need to be reviewed and approved by the POCC before using a new lot. Prior to using the new lot, the lot number and expiration date must be noted in the graph and logbook.

Out-of-Range Quality Control Procedure:

Note: DO NOT RUN PATIENT SPECIMEN until control values obtained are within range.

1. In cases where quality control results are outside of an acceptable range, the cause is likely attributable to one of the following categories:
   a. Test Technique
   b. Control Material
   c. Test Cuvette
   d. Instrument
2. If results are outside of the acceptable range, the following items should be verified immediately:
   a. Control material and cuvette expiration date
   b. Instrument temperature
   c. Proper technique
   d. Presence of clots in the control material
3. If none of the above parameters is suspect, repeat the test using control materials with the identical lot number.
4. If this repeat does not fall within the expected range, verify the above (a-d) parameters again. Obtain a cuvette from a different lot number and repeat the test using a control with the same lot number.
5. If this repeat test still does not fall within the expected range, notify the Department Supervisor and POCT Coordinator at ext. 73684 or 73153.
6. Obtain control material with a different lot number, and repeat the controls again.
7. If this repeated control does not fall within the expected range, discontinue testing and contact Accriva Diagnostics at 1-800-631-5945 for assistance, 8:00am – 5:30pm EST.
8. Document out-of-range results on the Quality Control and Patient log sheet and/or Corrective Action Log.

PROCEDURE – PATIENT TEST:

The Hemochron® Signature Elite Microcoagulation Systems can be operated either on its internal battery or plugged into an AC outlet. NOTE: Refer to

"Troubleshooting" should a fault message appear on the display at any time during this procedure.

1. Turn ON the instrument pressing the START button until ACCRIVA is displayed on the screen. The screen will then display **INSERT CUVETTE**.
2. Verify that the instrument has enough power to perform the test by visually checking the battery charge status indicator on the upper right hand corner of the instrument. Attach instrument to AC/DC Power Module if needed.
3. Insert the ACT-LR cuvette into the cuvette opening on the right side of the instrument.
4. The instrument will display **ENTER OID**, enter/scan your operator employee ID#, then press ENTER until **STORED** is displayed.
5. At the prompt, ENTER PID, enter/scan patient's 10 digit FIN number. You will hear an audible sound after entering the 10 digit. Press **ENTER** until **STORED** is displayed.
6. The messages **PRIMING PUMP** and **WARMING** will then appear on the display. During pre-warm stage, observe the display for any fault messages.
7. The instrument will signal when ready with an audible tone, and the screen will display the alternating messages **ADD SAMPLE** and **PRESS START**.

   Note: The instrument will remain in the ready mode for five minutes. At the end of five minutes, a "START TIMEOUT" will occur indicating that the current cuvette must be discarded and a new cuvette placed in the instrument.

8. Obtain fresh whole blood sample and dispense one drop into the sample well of the prewarmed ACT-LR test cuvette.
9. Fill the sample well from the bottom up with whole blood. A sufficient quantity of blood must be added directly to the center of the sample well to fill it flush to the top.

   Note: Should a large drop of blood extend above the top of the center sample well creating a dome, simply push it over into the outer sample well. When transferring blood into the sample well, DO NOT force blood into the pin located on the center of the sample well, and DO NOT generate air bubbles in the sample well.

10. Press the **START** key.
11. Test completion is indicated by a single beep.
12. ACT result is automatically converted to a reference Celite ACT result and displayed as the Celite equivalent result in seconds.
13. Record ACT result in log provided and to the patient's Electronic Health Record.
14. The screen will display **TEST COMPLETED, REMOVE CUVETTE**. Proceed with the next testing by inserting a fresh ACT-LR cuvette into the cuvette opening at the right side of the instrument. Follow steps 2-13.

INTERPRETING AND REPORTING PATIENT TEST RESULTS:

- Notify MD of all ACT results. ACT test results are monitored by the physician at the time of patient procedure.
- All ACT results must be properly documented in the patient's log and EHR (Electronic Health Record).
- All ACT results must be accompanied by a therapeutic range.
- Physician is completely responsible for using results outside the target therapeutic range.

THERAPEUTIC RANGE:

Baseline : <160

Extracorporeal Membrane Oxygenation (ECMO)+: 180 - 220 Seconds

Interventional Radiology: 250 – 350 Seconds

Cardiac Catheterization Lab (w/ and w/o Glycoprotein IIb/IIIa inhibitor [GPI]:
IV GPI: 200 – 250 Seconds
No IV GPI: 300 – 350 Seconds

ANALYTICAL MEASUREMENT RANGE:

ACT-LR : 65 – 400 seconds

PROFICIENCY TESTING:

Olive View-UCLA Medical Center participates in a proficiency testing survey two times a year through the College of American Pathologist. The unknown tests are performed by trained operators at the testing site and must be rotated among the performing staff and analyzed in the same manner as patient sample.

CORRELATION STUDY:

A correlation study at least twice annually is used to verify the comparability of patient results amongst the Hemochron® Signature Elite devices, to insure that patient results are consistently interpreted across the continuum of care. Fresh human samples (whole blood) are used to directly address whether a patient sample yields the same result on a different analytical instruments.

Correlation study will be performed twice a year.

CALIBRATION:

The Hemochron® Signature Elite instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are continuously monitored and verified by the instrument software when a test is performed. The instrument does not require additional calibration by the user.

SERVICE AND MAINTENANCE:

Daily Routine 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 dry cotton swabs. If a disinfectant is needed, use bleach wipes. Wipe instrument with a water-dampened cloth to remove residual bleach from the plastic surfaces.

Apply bleach wipes to disinfect areas contaminated with blood. DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components.

Service:
The Hemochron® Signature Elite instrument is almost completely self-monitoring and has no serviceable parts.
It monitors internal circuitry and reports problems to the display screen automatically. Malfunctions are indicated by error messages detailed in "Troubleshooting,"

Battery Care:
To optimize battery life, it is recommended that the instrument is plugged in overnight to allow the batteries to recharge and run on its battery during the day. When the batteries are drained to the point that valid testing cannot be performed, the instrument will display "CHARGE BATTERY". At this point, the instrument must be plugged in for operation and recharging. Once plugged into an AC/DC outlet, the instrument can be used immediately.

PROCEDURE NOTES:

1. Do not open the instrument, as there are no user-serviceable parts.
2. Do not remove the AC/DC power module from the instrument by pulling on the cord.

3. Do not use cuvettes that are past their marked expiration date or have been improperly stored.
4. 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.
5. Do not use excessive force in pressing the instrument keys.
6. Do not expose the instrument to extreme temperatures (above 50°C).
7. Do not drop the instrument, and do not use the results if the instrument is dropped during a test.
8. Use of an AC adapter other than that provided with the instrument could lead to reduced safety or instrument damage.
9. All biohazard safety guidelines pertaining to the handling and diposal of human blood should be strictly adhered to when collecting and handling blood specimens and when operating the Hemochron® Signature Elite Microcoagualation instrument.

LIMITATIONS:

1. Celite equivalent ACT values over 400 seconds are not reported on the Instrument. Instead, an "Out of range – Hi" message will be displayed. Note: Celite equivalent ACT values that exceed 400 seconds due to extremely high sensitivity to heparin in the patients, do not represent an error in the test.
2. 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.
3. Samples with a hematocrit less than 20% or greater than 55% are not recommended due to an optical density outside the level of detection of the instrument.
4. The Hemochron Jr. ACT-LR is affected by poor technique including blood collection and the transfer of blood to the sample well. The quality of the blood specimen may be affected by:
   - Foaming or hemolysis of the sample
   - Clotted or partially clotted blood
   - Unsuspected anticoagulation
   - Lupus anticoagulant
5. As with all diagnostic tests, Hemochron Jr. 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.

TROUBLESHOOTING:

Instrument Error Messages
The error messages that may be displayed while operating the HEMOCHRON Signature Elite instrument are listed below. The probable cause and corrective

action are shown for each message. Some messages designate a test or sample fault. If needed, contact Accriva Technical Support by phone at 1-732-548-5700, by FAX at 1-732-548-9824.

Error Message	Cause	Corrective Action
RTC…FAULT	Cannot communicate with external Real Time Clock.	Contact Accriva Technical Support.
CHARGE BATTERY	Battery power depleted below predetermined level.	Connect to AC/DC Power Module and charge battery for 8 hours.
BATTERY FAULT	Battery is discharged.	Charge battery for 8 hours. If message persists, contact Accriva Technical Support.
EXTERNAL TOO HIGH	AC/DC Power Module voltage exceeds 12.7 volts.	Disconnect the AC/DC Power Module. Contact Accriva Technical Support
BATTERY TOO HIGH	Battery voltage exceeds 8.8 volts.	Disconnect the AC/DC Power Module. Contact Accriva Technical Support.
Heater Too Cool	Incubator remained below 36°C after 90 seconds of warming on external power or for up to 150 seconds on battery.	Repeat test, then charge battery. If message persists, contact Accriva Technical Support.
Heater Too Hot	Incubator exceeds 38°C for 2.5 seconds.	Repeat test with new cuvette. If message persists, contact Accriva Technical support.
Detector Fault	Light path between LED and detectors is blocked.	Repeat test with new cuvette. If message persists, contact Accriva Technical Support.
Detector Blocked	EQC is being run while a cuvette is inserted.	Remove the cuvette and repeat the EQC.
Sample Pos Fault	Sample has moved outside of testing area in cuvette.	Contact Accriva Technical Support.

Error Message	Cause	Corrective Action
ASSAY LOCKED CALL SUPERVISOR	The QC failure limit has been exceeded.	Remove the cuvette. Contact the POCT at X73153 & X73684
MACHINE LOCKED CALL SUPERVISOR	The EQC failure limit has been exceeded.	Contact the POCT at X73153 & X73684
Sample Not Seen	Sample has not reached front detector in specified time period.	Repeat test with new cuvette. If message persists, contact Accriva Technical Support.
Cuvette Removed	Cuvette was prematurely removed from instrument while testing in progress.	Repeat test with new cuvette.
Sample Too Large/ Sample Too Small	Excess or insufficient sample.	Repeat test with new cuvette.
Premature Sample	Sample was detected at front detector before specified time period. May occur if sample is added before pump-priming sequence is complete	Repeat test with new cuvette. If message persists, contact Accriva Technical Support.
MEMORY FAULT	Malfunction in the computer's memory.	Contact Accriva Technical Support.
START Timed Out	START key was not pressed within 5 minutes after entering ready mode.	Remove cuvette and repeat test with new cuvette.
Unsupported Assay	Cuvette cannot be identified by instrument	Remove cuvette and repeat test with new cuvette. Use Accriva cuvettes only.
User Abort	The test was aborted by the user	Repeat test.
Invalid Lot#	The barcoded cuvette or QC lot number label that was scanned was not recognized.	Check the label for damage, then repeat the scan.

Error Message	Cause	Corrective Action
Invalid Lot#	The incorrect format was entered for the lot number.	Repeat the entry using the correct format.
	The lot that was scanned does not match the cuvette test type.	Verify the test type, then rescan the lot.
Lot Expired	The cuvette and/or QC material that is being used has reached its expiration date.	Remove the cuvette and repeat the test using supplies that are within their expiration date.
Action Denied	Date/Time cannot be changed if QC Lockout is required, or Date/Time function is denied through Configuration Manager.	POCT needs to reconfigure instrument using HCM
Disallowed Assay	Assay performance has been prohibited via Configuration Manager	POCT needs to reconfigure instrument using HCM
Out of Range-Lo	Test result is outside clinical range. Sample has clotted prematurely, or did not mix correctly in cuvette. Bubbles may be present.	Repeat test with new cuvette.
Out or Range-Hi	Test result is outside clinical range.	Repeat test with new cuvette.
Check Time/Date	Low Battery or RTC has lost its Time/Date Tracking	Enter or verify Time & Date. Charge Battery.
Dark Photo Fault	Hardware malfunction.	Contact Accriva Technical Support.

REFERENCES:

Hemochron® Signature Elite Whole Blood Microcoagulation System Operator's Manual, International Technidyne Corporation, Edison, New Jersey
Hemochron® Jr Whole Blood Microcoagulation Systems Low Range Activated Clotting Time (ACT-LR) Cuvette Package Insert, Accriva Diagnostics
Hemochron® Jr Microcoagulation System directCHECK Whole Blood Control Package Insert, Accriva Diagnostics
Extracorporeal Life Support: The ELSO Red Book, 5th ed 2017

2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.J Am Coll Cardiol 2014; 63 (25 Pt B)

References:	
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