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1.0 INTRODUCTION:

The portable, battery operated Hemochron Elite is a microcoagulation instrument designed to performed whole blood coagulation tests using fresh whole blood in a point‑of‑care setting.

Activated Clotting Time (LR) testing may be performed by Nurses (RN, LPN), Physicians, and Technicians assigned to the Interventional Radiology, Cardiac Catheterization, or Operating Room sections who have been annually in-serviced and deemed qualified by the manufacturer’s representative and/or the Laboratory Service Ancillary Testing Coordinator.

GENERAL POLICIES:

General policies have been established that meet current VA, CAP, JCAHO, CLIA’88, and CLSI guidelines. The following procedures have been established to ensure quality Activated Clotting Time (LR) testing in whole blood.

a. SAFETY: Due to the hazardous nature of the testing materials, it is necessary that disposable gloves be worn when handling specimens and when performing patient and QC test procedures. All specimens should be handled as recommended for any potentially infectious material in the Center for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories,” 1984.

b. The Chief, Pathology and Laboratory Medicine Service/designee, the Laboratory Ancillary Testing Coordinator, and all Testing Personnel will review policies and procedures pertaining to ACT-LR testing on an annual basis. This review will be documented on a Procedure Manual Documentation form.

c. Changes to the text as they apply to methodology or testing policy are signed by the Chief Pathology and Laboratory Medicine Service/designee, dated, and inserted in the policy/procedure manual.

d. Obsolete or superseded procedures are replaced in the procedure, but retained for filing and legal purposes for two years.

e. Medical Center Memorandum 00-30 “Patient Identification” is adhered to for patient identification practices.

2.0 PRINCIPLE:

The Hemochron Elite ACT‑LR 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 (PTCA).

The Hemochron Elite Microcoagulation Systems utilize a mechanical endpoint clotting mechanism in which testing occurs within the disposable ACT‑LR cuvette. Following whole blood sample introduction, the Hemochron Elite Microcoagulation Systems precisely measures 15 microliters of blood and automatically moves it into the test channel within the ACT‑LR cuvette. The remainder of the blood specimen, not used in 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 then moved back and forth within the test channel and monitored for clot formation.

The clot detection mechanism consists of two LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves between the two detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The Hemochron Elite recognizes that the clot endpoint has been achieved when the movement decreases below a predetermined rate. The instrument's digital timer displays the celite equivalent ACT value in seconds.

3.0 SPECIMEN:

3.1 Patient Preparation

a. NPO (food or liquid) from midnight before scheduled day of testing.

b. If the patient is on heparin:

1. Venous Procedure: Heparin should be discontinued upon notification

to the test site.

2. Arterial Procedure: Heparin should be discontinued 1‑4 hours prior to

the start of the procedure.

c. If the patient is on Coumadin: Discontinue coumadin 48‑72 hours prior to

the start of procedure.

d. EKG, BUN, Creatinine, PT, PTT, and platelet studies should be completed

and documented prior to (up to 30 days) the procedure.

3.2 Type

a. Syringe sample from indwelling line (whole blood).

b. Syringe sample from a venipuncture (whole blood).

c. Finger stick puncture (whole blood).

3.3. Handling

a. Blood samples to be used for coagulation testing must be collected in a

manner to prevent contamination with tissue thromboplastin, indwelling

intravenous (I.V.) solutions or alcohol cleansing solution that interfere

with coagulation assays. Poorly collected blood samples with visible

clotting or debris accumulation must be discarded and a fresh sample

collected. Samples with hematocrit of <20% or >55% are not

recommended due to an optical density outside the level of detection of

the Hemochron Elite instrument.

b. Blood collection guidelines are outlined in CLSI H21‑2A, "Collection,

transport and preparation of blood specimens for coagulation testing

and performance of coagulation assay” (attachment).

c. Use standard blood borne precautions during procedure.

3.4. Collection Method

a. Syringe sample from indwelling line: The amount of blood required to

adequately flush the line until it is free of contaminants is dependent on

the amount of solution contained within the line. A typical heparin lock

will require approximately 5cc to clear the line. Greater volumes will be

required to clear longer lines.

b. Syringe sample from a venipuncture:

1. Using a two-syringe technique, fill the first syringe with 2.0cc of blood

and discard.

2. Collect 0.2cc from a second syringe for testing purposes.

c. Obtain a finger stick sample. Wipe finger with alcohol. Perform finger

stick puncture. Wipe away the first drop of blood with sterile dry gauze.

Gently massage the finger from base to tip collecting the next sample.

4.0 EQUIPMENT AND MATERIALS:

4.1 Equipment

a. Hemochron Elite Whole Blood Microcoagulation System.

Manufactured by ITC, Edison, NJ 08820.

Technical Support 1-800-631-5945.

b. Transformer: 12 volt supplied with Signature Elite instrument.

4.2 Materials

a. Hemochron Jr. ACT‑LR test cuvettes (Catalog No. JACT-LR) preloaded

with dried preparation of celite, stabilizers, and buffer. Purchased from

ITC, Edison, NJ 08820.

1. When refrigerated (2-8ºC) the foil-pouched ACT-LR cuvette is stable until the marked expiration date.
2. Room temperature storage (15-30ºC) is optional for sealed-pouched cuvettes. Room temperature cuvettes are good for a maximum of twelve weeks, but must never exceed the marked expiration date. Re-dating is necessary if stored at room temperature.
3. Once pouch is opened, the cuvette (stored in folded pouch) is stable for **only one day** under refrigerated (2-8ºC) conditions.
4. Hemochron Jr. cuvettes should not be exposed to temperatures in excess of 37ºC.

b. directCHECK Whole Blood Control - Normal (Catalog No. DCJLR-N) and

Abnormal (Catalog No. DCJLR-A). Purchased from ITC, Edison, NJ 08820.

1. When refrigerated (2-8ºC) the whole blood quality control material is stable until the marked expiration date.
2. Room temperature storage (15-30ºC) is optional for sealed whole blood controls. Room temperature controls are good for a maximum of four

weeks, but must never exceed the marked expiration date. Re-dating is necessary if stored at room temperature.

1. The whole blood quality control material should not be exposed to temperatures in excess of 37ºC.
2. Reconstituted vials should be used immediately.

c. 1cc or 3cc plastic syringes with 23 or 21 gauge needle (optional).

4.3 Preparation

a. No reagent preparation is required. The ACT‑LR test cuvette is a self-contained

disposable test chamber preload with a dried preparation of celite, potato

dextrin, stabilizers and buffers.

b. Whole blood quality control material and ACT‑LR test cuvettes must come

to room temperature before using. This could take up to 60 minutes.

4.4 Performance Parameters

a. The Hemochron Jr. Low Range ACT demonstrates linear correlation to

the anticoagulant effects of heparin up to 2.5 units/cc of blood.

b. Manufacturer’s Specifications: Precision of Test: CV <14%

Incubation Temperature: 37ºC +/‑ 1.0ºC.

c. ITC Technical Service Department 1-800-631-5945 is to be notified of any

"fault" messages.

5.0 QUALITY CONTROL:

5.1 System Self‑Check

The HEMOCHRON Elite microcoagulation 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:

a. Verification of adequate battery power to complete a full test.

b. Verification of the test‑type on the screen display to insure that the Liquid

Electronic Diodes (LED's) used for identifying the tests are functioning properly.

c. Verification that the cuvette temperature is warmed to 37ºC +/‑ 1ºC. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.

d. Verification that the sample is present and is of sufficient size to run the test. This insures that the pumps and sample sensing LED's 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.

e. 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.

5.2 Auto Electronic Quality Control (EQC)

Internal EQC will check two levels of QC plus the temperature. It will store each result. If one result fails, the test will stop and record all results as failed.

a. EQC for the Elite assists in accomplishing daily QC, internal EQC is used to provide a two-level electronic verification of instrument performance. EQC will be performed

automatically every 8 hours, or the first time the Elite is turned on after 8 hours.

b. If any electronic procedure yields an on‑screen ERROR message, discontinue

use of the instrument, document finding on the corrective action log and notify

the ITC Technical Support 1-800-631-5945 for assistance.

c. Normal Level: 30 seconds. Acceptable range 29‑31 seconds.

Abnormal Level: 500 seconds. Acceptable range 499‑501 seconds.

Temperature: 37º +/- 1ºC.

Results are displayed on the screen and written to the QC database.

5.3 Manually performing EQC

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

b. Press 1. The test chamber warms to temperature and the EQC test begins. The

results are displayed while the test is progressing.

c. When the test is completed, the results are displayed on the screen and written

to the QC database.

5.4 Quality Control of the Hemochron Elite Test Cuvettes

Note: Quality Control samples are tested in the same manner as patient specimens and

by the same operators to the greatest extent possible.

a. Liquid Quality ControlTesting is normal and abnormal quality control material

(directCHECK Whole Blood Control) to be run once per week prior to patient

testing and when a new box of cuvettes is opened.

1. Remove the ACT‑LR test cuvettes and 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).

2. Visually inspect the directCHECK vial to insure that the glass ampule is intact.

3. Turn the Elite on by pushing the “START” button.

4. When prompted enter the Operator ID number (OID).

5. After the reagents have reached room temperature, insert the ACT‑LR cuvette

into the cuvette slot on the side of the instrument. Note: During the pre‑warm

stage, observe the display for any fault/warning messages.

6. The instrument will signal when ready with an audible beep, and display the messages, "Add Sample" and "Press Start".

7. Press the “QC” button.

8. Press the number 1 to run the Normal Control or 2 to run the Abnormal Control.

9. Remove the top of the plastic seal from the directCHECK vial selected in the Elite.

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

11. Holding the vial upright, tap the directCHECK vial on the table top to settle

the inner glass ampule to the bottom of the vial.

12. Crush the inner glass ampule by either bending the vial over the edge of a

table top or by crushing the vial between two fingers.

13. Immediately repeat this crushing action one to two more times to ensure

complete breakage of the glass ampule.

14. Quickly shake the dropper vial end to end 10 times.

15. While inverting the vial (dropper tip down), 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 with vial dropper.

19. Press the “START” key.

20. Recap the control vial and remove the control vial from the protective sleeve.

21. Dispose of vial and vial cap appropriately and retain protective sleeve for reuse.

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

23. Results are displayed as the Celite equivalent clotting time.

24. Result ranges are programmed into the Elite. If a liquid control falls outside of

the pre programmed ranges the failed level should be repeated. After 4 attempts

to get the control within the programmed range, the Elite is locked and must be

reset by the ATC (Ext 4412).

b. Out Of Range Quality Control Procedure

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 dates

b. Instrument temperature

c. Proper technique

d. Cuvette sample volume

e. Presence of clots in the control material

3. If the above parameters are not 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‑e)

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 does not fall within the expected range, verify the above (a‑e)

parameters again. Obtain control material with a different lot number, and

repeat the controls again.

6. If this repeat test still does not fall within the expected range, notify the

Ancillary Testing Coordinator at X-4412. After hours contact ITC Technical

Service at 1-800-631-5945. Document the problem and any follow-up

corrective action to resolve the problem.

c. Proficiency Testing

1. VAMC Pathology and Laboratory Medicine Service is enrolled in the College of

American Pathologists (CAP) approved CT2 Survey for ACT‑LR testing.

2. All CT2 samples should be considered potentially infectious and should

be handled as though they are capable of transmitting disease.

3. Proficiency samples will be handled in the same manner as samples collected

from a patient, therefore it is extremely important that all "standard precautions"

are followed and observed.

4. ACT‑LR proficiency testing will be received on a semiannual basis. Random

operators will be selected to perform testing.

5. Interlaboratory communication about proficiency test samples is prohibited until after the deadline for submission of data to the proficiency testing provider.

6. Referral of proficiency test specimens to another laboratory is prohibited.

6.0 PROCEDURE:

1. Insert cuvette into the cuvette opening of the instrument. The cuvette must be inserted with the blood reservoir facing up. The instrument will automatically identify the test cuvette and display the test type.

2. Enter Operator ID (OID) when prompted.

3. Verify identity by asking patient to state their full name and Social Security Number.

4. Enter Patient ID (PID) when prompted. This should be performed using the patient

bar coded wrist band. Manual entry of the PID is possible.

5. During the pre‑warm stage, observe the display for fault messages.

6. When ready, the instrument will signal with an audible tone. The display will

indicate the alternating messages "Add Sample" and "Press Start". The instrument

will remain in the ready mode for 5 minutes before a "START timeout" will occur

requiring a new cuvette to be placed in the instrument.

7. Obtain Sample. Refer to section 3.3 "Specimen Handling" for specific instructions.

8. **Immediately** dispense one drop of blood into the center 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 to the

center well to fill it flush to the top. Should a large dome of blood extend above

the center sample well, push it over into the outer sample well.

9. Depress the START key. A single beep will signal the start of the test. Note: The instrument displays "Sample too large" or "Sample too small" if an excessive or inadequate sample volume has been provided.

10. Test completion will be indicated by a single beep. Note: Two beeps are indicative

of a fault condition.

11. Upon clot detection, the ACT‑LR test result is automatically converted to a Celite

equivalent value in seconds and displayed. The test results will remain on the display

screen until the test cuvette is removed from the instrument..

12. Results are reported directly to the physician performing the procedure.

7.0 CALCULATIONS/INTERPRETATION:

No calculation is required. Results are reported directly from the instrument in Celite equivalent seconds.

8.0 REPORTING RESULTS:

1. All ACT‑LR results are reported directly to the requesting physician/provider.

2. The Hemochron Elite will automatically upload all ACT-LR results for review of

pre-defined criteria by the Medical Automation RALS Plus “evaluator” system.

(See Section 13.0 Downloading Elite into RALS.)

3. The RALS Plus “evaluator” software filters all results as received and one of two

scenarios occur:

a. results will be allowed to be passed directly into VistA.

b. results will be flagged for secondary review by the ATC.

4. In addition to the pre-defined criteria, the RALS Plus system is a bi-directional interface which can either pass a result successfully into VistA or flag it back to the “Flagged Results” page with the reason for failure indicated.

a. Interface failure scenario – Interface detected failures are caught prior to the upload. Incorrect patient identification (wrong Social Security Number entered into Elite) is the primary reason. They are flagged as “Invalid Patient ID, not recognized by VistA”. These results will remain in the flagged results page and will not be uploaded to VistA.

b. ADT (Admission, Discharge, Transfer) failures occur when VistA is not provided with specific information pertaining to the patient (e.g. location, provider). These results will be reviewed in CPRS and manually entered into VistA by the ATC when appropriate.

9.0 RESULT NOTES:

9.1 Reportable Range: 60‑400 Celite equivalent seconds.

Manufacturers' Reference Range: 113‑149 seconds

(Normal range generated from volunteer donors.)

Manufacturers' Reference Range: 89‑169 seconds

(Normal range generated from hospitalized patients not receiving heparin.)

9.2 Ranges for Indwelling Vascular Sheath Removal

(Manufacturers’ range generated from 20 patients at the completion of Percutaneous Transluminal Coronary Angioplasty or 5 to 24 hours following the heparin bolus in the CCU when the indwelling vascular sheath was to be removed.)

Clotting Time at Sheath Removal

ACT-LR

N Mean SD Range

(secs.) (secs.) (mean +/- 2 SD)

20 145 31 81-207

9.3 Procedure for Abnormal Results

a. Results that exceed “400” should be reported as “greater than 400”.

b. ALL results will be reported directly to the requesting physician/provider,

downloaded from the Elite, and entered into VistA by the RALS Plus “evaluator”. (See Section 13.0 Downloading Elite into RALS.)

c. Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be repeated immediately on a fresh sample.

9.4 Reporting Format

Celite equivalent seconds.

10.0 LIMITATIONS OF THE PROCEDURE:

1. Specimen with hematocrit readings of <20% or >55% are not recommended due

to optical density outside the level of detection of the Hemochron Elite instrument.

2. Refer to the Hemochron Elite Microcoagulation Instrument Operator's Manual

for additional information about:

* System features
* Keypad features
* Service and maintenance
* Troubleshooting
* Warranty and repair policy

11.0 PROCEDURAL NOTES:

1. 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.

2. DO NOT use cuvettes past the expiration date or that have been stored improperly.

3. 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 Maintenance)

4. DO NOT use excessive force in depressing the START key.

5. **DO NOT drop the HEMOCHRON**.

6. DO NOT expose the HEMOCHRON to extremes in temperature (above 37º C). Such

exposure could affect the performance of any type of electronic equipment.

7. The HEMOCHRONs are designed for use only with HEMOCHRON Jr. test cuvettes.

8. HEMOCHRON microcoagulation system 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. Tests may be affected by any of the following conditions:

a. Foaming of the sample (air bubbles)

b. Hemolysis

c. Clotted or partially clotted blood

d. Unsuspected anticoagulation with either heparin or warfarin

e. Presence of a lupus anticoagulant

9. All biohazard safety guidelines pertaining to the handling of human blood, such as the CDC guidelines of Universal Precautions, should be strictly adhered to when collecting, handling blood specimens and operating the HEMOCHRONs. Refer also to CLSI standard H21‑2 for Collection, Transport, and Processing of Blood Specimens for Coagulation testing and General Performance.

10. Used HEMOCHRON Jr. test cuvettes should be considered as potentially infectious. They should be disposed of in a designated “sharps” container.

11. HEMOCHRON microcoagulation instruments are not rated for use in explosion proof areas.

12.0 MAINTENANCE:

12.1. Routine Maintenance

a. 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.

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

c. Routine maintenance other than cleaning is not required.

12.2. Service

a. The HEMOCHRON microcoagulation instruments are almost completely self monitoring; automatically monitoring internal circuitry and reporting problems to the display screen.

b. Malfunctions are indicated by fault messages detailed in the section on TROUBLESHOOTING in the HEMOCHRON Elite’s System Operator's Manual.

12.3. Battery Care

a. The HEMOCHRON Elite can be operated either on internal battery or plugged into an AC outlet using the supplied transformer.

b. The Signature Elite should be allowed to charge for a full 8 hours prior to using the instrument for the first time.

c. A fully charged battery will operate for 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.

d. 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 in the instrument as soon as possible.

e. 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 in for operation and recharging. Once plugged into an AC outlet, the instrument can be utilized, and testing resumed.

12.4. Instrument Downtime

a. During instrument downtime, patient samples may be run on an alternate HEMOCHRON Elite. Elite locations are: Interventional Radiology (2) and Cardiac Catherization Lab (2), Operating Room (2).

b. If service is necessary and the instrument must be shipped to ITC, contact the Biomedical Department to obtain the necessary paperwork. **No loaner** Elite will be obtained from ITC while service is being performed.

13.0 Manual Downloading Elite into RALS – The Elite should manually download after each

test. If this does not occur, you should manually download.

1. After performing the final test for your case or at the end of the day, push the **PRINT/SCAN** button.
2. Press the number **“6”- Print Check**.
3. The Elite then shows **“PC Link”** on the display panel.
4. The Elite then returns to the Print/Scan screen on the display panel.
5. Downloading is successful when the **“PC Link”** occurs.
6. If **“PC Link”** does not occur, please notify the Ancillary Testing Coordinator at X-4412.

14.0 REFERENCES:

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9. ITC Hemochron Signature Elite Whole Blood Microcoagulation System Operator’s Manual

May 2005.