HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY – POINT OF CARE POLICY MANUAL

HEMOCHRON SIGNATURE ELITE
ACT – Activated Clotting Time

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Policy No: POC CL 0001
Origin: Point of Care Tests
Authority: Laboratory Director

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SCOPE; Catherization (Vascular) Lab and OR.

PURPOSE: It is intended for use in monitoring low to moderate heparin doses frequently associated with vascular procedures and to indicate the coagulation state for safe removal of femoral sheaths.

DEFINITIONS:
ACT-LR = Activated Clotting Time Low Range
EQC = Electronic Quality Control
LQC = Liquid Quality Control

POLICY:
1. EQC is automatically checked every 8 hrs.
2. Two levels of liquid QC – Normal & Abnormal - are run for each day of patient testing and for every new lot of cuvettes.
3. Lot to lot testing must be performed for new lot of cuvettes.
4. Only certified clinicians can have access to the device. A 6 month re-certification is required on the first year of training and yearly thereafter the initial year. Overdue competency will be completely locked out.
5. For troubleshooting guide, call POC Coordinator first (Cris Hom) at 6849 or ITC Technical Support at 800-631-5945 ext 707.
6. Follow Standard Precautions protocol – gloves must be worn throughout patient and QC testing, perform hand hygiene before and after leaving patient's room, and change gloves between patients.
7. Linearity range 65- 400 secs. Repeat results >400 secs.
8. Therapeutic range 200 – 350 secs.
9. Normal reference range 125 - 153secs.

EQUIPMENT & MATERIALS:
1. Hemochron Signature Elite device
2. Hemochron Jr. ACT-LR test cuvettes
3. 10cc or 3cc syringe.
4. 18g needle
5. Liquid quality controls (*direct*Check)
6. Gloves.

STORAGE:

Hemochron ACT-LR test cuvettes must be stored in the refrigerator (2 - 8°C), stable until the marked expiration date. Room temperature re-dating of unopened pouch is up to a maximum of 12 weeks but not to exceed the marked expiration date. Once a pouch is opened, the cuvette (stored in the folded

pouch and refrigerated) is stable for 7 days.

Liquid quality control materials (*direct*CHECK) must be stored in the refrigerator (2 - 8°C), stable until the marked expiration date. They may be stored at room temperature for up to 4 weeks but not to exceed the marked expiration date. Re-dating label should be marked with 4 weeks dating if room temperature storage is selected. Reconstituted vials must be used immediately.

PATIENT PROCEDURE:

1. Start the instrument by pressing the **START** key and wait for the instrument to prompt you that it is ready to accept a cuvette.
2. Place a cuvette (make sure the cuvette has reached a room temperature).
3. Scan lot number of the cuvette from the package.
4. Scan the operator ID badge.
5. Scan the patient armband press **ENTER** (hold it down for a couple of seconds). When entering manually it must be entered 2X and numbers must match. Verify the ID numbers on the meter.
6. When **ADD SAMPLE** displays, add the sample in the sample well and avoid generating air bubbles. **PRESS START** (hold it down for 2 sec).

NOTE: To collect blood sample (sample must not be collected until the instrument display indicates "Add Sample and Press Start"):

A. Remove luer lock cap from sheath port.
B. Clean the sheath port with an alcohol swab.
C. Obtain and discard 10cc of blood from sheath. Then immediately withdraw 3cc of blood sample from the same port.
D. Flush sheath with 10cc of heparinized saline and re-attach the luer lock cap.

7. The elapsed time (in seconds) is displayed until a clot is detected.
8. Final results of the test are calculated and displayed.
9. Enter result in Cerner under POC and **enter 1** for quantity.
10. Remove cuvette and discard it in a biohazard container.

ELECTRONIC QUALITY CONTROL PROCEDURE (EQC) – DAILY:

NOTE: Instrument temperature is automatically checked whenever EQC is carried out (every 8 hrs). The instrument temperature is maintained at 37°C +/- 1.0°C. If the temperature reading is out of range, please contact the POC coordinator in the lab (6849) or call the ITC Technical Support at (800 631- 5945).

1. Start the instrument by pressing and holding down the **START** key (Do not insert a cuvette, otherwise, the EQC test will be aborted). Instrument can also be left on so EQC can be automatically be done every 8 hrs.

2. The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing. The internal EQC will check two levels of QC and the temperature and it will store each result. If one result fails, the test will stop and record all results as failed.

LIQUID QUALITY CONTROL PROCEDURE (LQC/NORMAL/ABNORMAL):

NOTE: <u>RUN LQC</u> will display if 24 hrs has passed since the last QC. <u>CHECK LQC</u> will display after LQC have been run.

1. Remove test cuvettes and control materials (*direct*CHECK) from the refrigerator and allow them to come to room temperature (15 - 30°C) prior to testing.
2. Insert a test cuvette into the cuvette slot on the side of instrument.
3. Scan the lot numbers of the cuvette from the package.
4. Scan the operator's badge ID.
5. **Press QC** then choose the correct either Normal or Abnormal.
6. During pre-warm stage, observe display for fault/warning messages.
7. The instrument will signal ready with an audible tone and display **Add Sample.**
8. Immediately reconstitute the dropper vial contents as follows (you have 5 minutes to do this):
    A. Remove the label from the vial. Visually inspect vial to ensure that the glass ampule is intact.
    B. Insert vial into protective sleeve and holding vial upright.
    C. Crush the inner glass ampule over the edge of a table top or by crushing the vial between two fingers.
    D. Crush at the top, middle and bottom of the ampule.
    E. Quickly shake the vial end to end about 10 times.
9. Remove and retain the vial cap. Squeeze the vial to discard the **first drop** into the vial cap.
10. Immediately dispense as many drops of control material as needed to fill the cuvette sample well flush to the top (if there's too much liquid, sweep the excess to the side of the well).
11. Press the **Start and hold for 2 sec**.
12. Recap the control vial and remove it from the protective sleeve. Dispose of the vial and vial cap appropriately but retain the protective sleeve for reuse.
13. Wait for the single beep signaling end of test.
14. Check the acceptable range for each level of QC on the back page of package insert. Both levels must be in range. Out of range QC must be repeated.
15. Remove the cuvette from the instrument and dispose it in a biohazard container.

MAINTENANCE:
Monthly:
1. Inspect and clean the cuvette opening monthly.
2. Remove residual dried blood or other foreign matter using water moistened cotton swabs.

3. Remove any residual water with a dry cotton swab.
4. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water.
5. 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.

LIMITATIONS:

Samples with a hematocrit < 20% or > 55% are not recommended due to an optical density outside the detection level of the instrument. Variations in ambient temperatures should be minimized for consistency of test performance. ACT values over 400 seconds due to extremely high sensitivity to heparin in patients do not represent an error in the test.

REFERENCES:

1. International Technidyne Corporation, ITC, operator's manual, issued 03/07.
2. Package insert for *direct*CHECK whole blood control.
3. Package insert for Low Range Activated Clotting Time (ACT-LR) cuvettes.