HEMOCHRON® SIGNATURE ELITE ACT+ procedure

This procedure provides instructions on how to perform Activated Clotting Time (ACT) on the Hemochron® Signature Elite

The Hemochron® Signature Elite is a point-of-care coagulation testing system. When used with the Hemochron® Jr. Activated Clotting Time Plus (ACT+) cuvette, it provides a quantitative assay for monitoring heparin anticoagulation during various medical procedures when high doses of heparin are used.

Location: Cardiac OR at BC Children's Hospital

Samples:

Sample Collection

The Hemochron® Jr. ACT+ test is performed using fresh whole blood obtained by syringe from the extracorporeal circuit.

The Hemochron® Jr. Cuvette employs a kaolin activator and is only cleared for the monitoring of heparin.

Please not 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)

Unacceptable Sample Types

Samples with any of the following characteristics are unacceptable for testing:

- Sample collected into a pre-heparinized syringe
- Sample contamination with tissue thromboplastin
- Sample contamination with indwelling intravenous solutions
- Sample contamination with alcohol cleansing solution
- Samples with visible clotting or debris accumulation.

Materials

Reagents	Equipment	Supplies
• Hemochron®Jr. ACT+ test cuvette (insert item order #)	• Hemochron® Signature Elite (There are 2 validated instruments for use). • AC/DC power module (for use when charging the device)	• plastic on-heparinized syringe (insert item order #) • *direct*CHECK® Whole Blood Quality Controls, 2 levels (Catalog numbers: DCJACT-A and DCJACT-N)

Hemochron® Jr. ACT+ test cuvette cartridge stability reagent

Reagent	Temperature	Stability
Hemochron® Jr. ACT+ test cuvettes	Fridge at 2 to 8°C	Until expiry
	Unopened at RT 12 weeks	12 Weeks
	Open at RT	24 hours
*direct*CHECK® Whole Blood Quality Controls	Unopened at RT	12 weeks
	Fridge at 2 to 8°C	Until expiry

Quality Control:

Quality Control	Frequency
Electronic Simulation Control (EQC)	At start up and every eight (8) hours while in use
Liquid QC	Every 30 days and/or with a new lot and/or shipment of cuvettes.

Procedure 1.0 How to perform the Electronic Quality Control

	Action	Related Documents Title Number
1.	EQC provides two-level electronic verification of instrument performance and is to be performed at start up and every eight (8) hours while in use.	
2.	The Internal EQC will check the following parameters: 1. Normal level (30 ACT seconds), 2. Abnormal level of QC (300 ACT seconds or 500 ACT seconds) 3. Internal temperature	
3.	To perform the EQC follow steps 4 to	
4.	Press the "QC" key before a cuvette is inserted to get the QC status menu 	
5.	Press "1-EQC". The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing.	
6.	When the test is completed, the results are displayed on the screen and written to the QC database.	
7.	If the test fails, repeat the process.	
8.	If the repeat test fails, or if the EQC procedure yields an on-screen ERROR message, do not use for patient testing and contact the POCT technologist	
9.	Each result will be stored on the instrument	
10.	If one of the parameters in step 2 fails the entire EQC will be resulted as failed.	

	Action	Related Documents Title Number
11.	If the user aborts the EQC, the test is not saved to the database or printed.	
12.	Document on the QA sheet that the EQC was performed and was successful.	

Procedure: 2.0 How to perform the liquid QC on the Hemochron

	Action	Related Documents Title Number
1.	Liquid QC is performed every 30 days and/or with a new shipment or lot of cuvettes.	
2.	As recommended by the vendor two levels of liquid quality control, normal and abnormal range must be run once: 1. Every 30 days 2. With every shipment of cuvettes 3. With evert new lot # of cuvettes	
3.	To perform the liquid qc follow steps 4 to _ t	
4.	Remove the *direct*CHECK vials, one each normal and abnormal, from the refrigerator and allow them to come to room temperature prior to testing	
5.	Remove two cuvettes from the refrigerator and allow them to come to room temperature. The foil pouch must be at room temperature before opening.	
6.	Visually inspect each vial to ensure that the glass ampule inside the plastic vial is intact.	
7.	Press “QC” soft key and select QC level (1-Normal or 2-Abnormal) to tag the sample.	
8.	After the reagents have reached room temperature, open the cuvette pouch and insert into the cuvette slot on the side of the instrument.	
9.	The instrument will signal when ready with an audible beep, and display alternating messages: “Add Sample” and “Press Start”.	
10.	The instrument will remain in the ready mode for five (5) minutes.	
11.	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.	
12.	Remove the top of the plastic seal from the *direct*CHECK vial.	
13.	Insert the *direct*CHECK vial into the white protective sleeve.	
14.	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.	
15.	Crush the inner glass ampule by bending the vial over the edge of a table top.	

	Action	Related Documents Title Number
16.	Immediately repeat this crushing action one to two more times at different locations of the vial to ensure complete breakage of the glass ampoule.	
17.	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.	
18.	Remove and retain the vial cap.	
19.	Squeeze the vial to discard the first drop of control material into the vial cap.	
20.	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.	
21.	Press the “START” key.	
22.	Dispose of the vial and vial cap according to institutional policy and retain the protective sleeve for reuse	
23.	Press the “START” key.	
24.	Dispose of the vial and vial cap according to institutional policy and retain the protective sleeve for reuse	
25.	Document the result of the liquid qc on the QC sheet. Please remember to include the following: 1. Lot number of the QC 2. Lot number of the Cuvette 3. Date 4. Operator ID	
26.	In cases where LQC results are outside of an acceptable range, the cause may be one of the following: Improper test or mixing technique Expired or improperly stored QC Material Expired or improperly stored cuvettes Instrument or material temperature	
27.	If none of the above parameters are suspect, repeat the test using LQC material of the same lot number.	
28.	If this repeat does not fall within the expected range, address the above parameters again	
29.	Obtain a cuvette from a different lot number and repeat the test using LQC material with the same lot number.	

	Action	Related Documents Title Number
30.	If this repeat test still does not fall within the expected range, do not use instrument for patient testing.	
31.	Notify the POCT technologist.	

Procedure 3.0: The System Self Check

	Action	Related Documents Title Number
1.	The Hemochron® Signature Elite performs a "Self-Check" with every test. When a test is initiated by inserting a cuvette or the "Start" key is pressed, a system check is automatically performed, which 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.	
	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.	

Procedure 4.0 How to perform patient testing on the Hemochron

	Action	Related Documents Title Number
1.	Please not 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)	
2.	Remove ACT test cuvette from the refrigerator and allow reaching room temperature.	
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.”	
9.	The instrument will remain in the ready mode for five (5) minutes. If the testing has not been started within five (5) minutes, a “Start timeout” will occur. In that case discard cuvette and obtain a fresh cuvette.	
10.	Obtain a fresh whole blood sample as previously outlined in this procedure.	
11.	Immediately dispense one large drop of blood into the sample well of the test cuvette.	
12.	Fill the sample well from the bottom up with fresh whole blood.	
13.	A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top.	
14.	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.	
15.	When transferring blood into the sample well, do not force blood into the pin located on the center of the sample well.	
16.	Do not generate air bubbles in the sample well.	
17.	Press the “START” key.	

	Action	Related Documents Title Number
18.	Test completion will be indicated by a single beep.	
19.	Record results.	
20.	Remove the cuvette from the instrument and discard.	
21.	Test results must be reported in the patient chart. Please include: 1. POCT result 2. Requesting physician or protocol 3. Date and time of sample collection 4. Date and time of test result 5. Name/initial/operatory id of person performing the test	
22.	Whole blood ACT+ test results less than 68 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.	
23.	Whole blood ACT+ test results greater than 1005 seconds will result in an "Out-of-Range-Hi" error message. This may indicate excessive blood anticoagulation and should be repeated to confirm the result.	
24.	Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be immediately repeated. Contact the POCT technologist if instrument or reagent performance is the suspected cause.	

Procedure: 5.0 Proficiency Testing

	Action	Related Documents Title Number
1.	Twice a year the POCT team will contact the OR to send three proficiency testing samples to test the Hemochron.	
2.	Please complete the samples and return the results to POCT Lab by scan and email to POCTlab@cw.bc.ca	

Procedure 6.0 How to perform routine maintenance

	Action	Related Documents Title Number
1.	Routine maintenance other than cleaning is not required.	
2.	Inspect and clean the cuvette opening as required.	
3.	Remove residual dried blood or other foreign matter using water moistened cotton swabs.	
4.	Remove any residual water with a dry cotton swab.	
5.	If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water.	
6.	Wipe instrument with a water-dampened cloth to remove bleach from the plastic surfaces.	
7.	DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components.	
8.	Inspect and clean the cuvette opening as required.	

Procedure 7.0: Reminders

	Action	Related Documents Title Number
1.	POCT Lab will contact the department every 3 months to gather the QA? QC sheets please scan and email the documents as requested.	
2.	The AC/DC 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.	
3.	Do not use cuvettes past their expiration date or cuvettes that have been stored improperly.	
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.	

	Action	Related Documents Title Number
5.	Do not use excessive force in pressing the “START” key.	
6.	Do not allow the instrument to hit any hard surfaces or fall.	
7.	Do not expose the instrument to temperatures extremes: below 15° C or above 37° C.	
8.	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.	
9.	Test results may be affected by poor technique during blood collection and delivery to the sample well.	

Procedure 8.0: Ongoing Training and competency

	Action	Related Documents Title Number
1.	On-going competency will be required annually and will require: 1. Review of the Hemcohron SOP 2. Performance of one level of QC	
3.	POCT Lab will work with the CNE to set up dates for the ongoing competency training.	
4.	Do not use cuvettes past their expiration date or cuvettes that have been stored improperly.	

Appendix A:
Hemochron HR ACT+ Training & Competency Checklist

Name (Please Print):	**Operator ID:**	**Department:**	**Trainer/s:**	**Date:**	
Operator demonstates knowledge &/or competency performance				**YES**	**NO**
1. **Battery / Power Supply. Instrument requires a charge when "Charge Battery message is flashing on-screen. 8 hr minimum charge.**					
2. External Cleaning. Caviwipes – do not use ACCEL TB wipes.					
3. **Hemochron ACT+ Test Cuvette-** Storage, expiry, open air exposure. Room Temp 3 months expiry; 4°C package expiry (1hr @ RT before use; up to 5 min.					
4. Electronic Quality Control (Internal) – DAILY (Q 8 hr)					
5. Quality Control (QC) Solutions – Level1 & Level2 – Storage & open Vial Expiry Room Temp 4 weeks expiry; 4°C package dating; (1 hr @ RT before use). QC vial handling and QC testing. Regimen to be established on implementation of the Hemochron Signature Elite ACT+ in COR.					
6. **Cuvette(ACT+) & QC Stock** – Laboratory Walk-in Fridge Rm. 2F50.					
7. Performs Daily Electronic Quality Control - documents on record form.					
8. **Performs Daily Liquid Quality Control L1 & L2 - d**ocuments on record form.					
9. **Review of QC results. Discussion** of corrective action when QC is out of range. Documents any action taken on the Hemochron APTT QC Record.					
10. **Patient identification** & sample application.					
11. Sample Collection – as per procedure – from the same syringe draw –& Hemochron ACT+. **Documented time of collection needs to correlate on the Medtronic ACT & Hemochron ACT+ forms.**					
12. Troubleshooting Guide – Error Codes (reverse of Quick Reference Guide)					
13. Standard precautions when performing the test. Appropriate disposal.					

Revision Log

Version	Description of Change	Revision Date
1.0	Formatted for QMS upload	Nov 23 2018
1.1	Added reference to update ePOPS	Feb 26, 2019

Attention: This document is published on the ePOPS website

Revisions made to this document require an update to the corresponding document published on ePOPS website