HEMOCHRON® SIGNATURE ELITE ACT-LR Procedure

This procedure provides instructions on how to perform Activated Clotting Time (ACT) on the Hemochron® Signature Elite in settings of low to moderate heparin doses.

The Hemochron® Signature Elite is a point-of-care coagulation testing system. When used with the Hemochron® Jr Low Range Activated Clotting Time (ACT-LR) cuvette, it provides a quantitative assay for monitoring heparin anticoagulation during various medical procedures when heparin is used. It is intended for use in monitoring low to moderate heparin doses frequently associated with procedures such as cardiac catheterization and Extracorporeal Membrane Oxygenation (ECMO).

ACT values from different assays or instruments are NOT interchangeable. Do NOT switch between different types of ACT tests or methods when monitoring a patient. Use only the ACT-LR when low to moderate heparin doses are being administered. This method exhibits considerable variability and anticoagulation status should be assessed in concert with other clinical and laboratory features.

Samples:

Sample Collection

The Hemochron® Jr ACT-LR test is performed using fresh whole blood. Collect samples as per clinical protocol.

The Hemochron® Jr ACT-LR Cuvette employs a Celite activator and is intended for monitoring heparin therapy.

Please note, 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)
- Aprotinin
- Hematocrit extremes (Hct <20% or > 55% will produce errors)

Unacceptable Sample Types

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

- Sample collected into a pre-heparinized syringe
- Sample collected in a glass blood collection tube
- Sample contamination with tissue thromboplastin
- Sampling from heparinized access line, lock or indwelling heparin lock
- Sample contamination with indwelling intravenous solutions
- Sample contamination with alcohol cleansing solution
- Samples with visible clotting or debris accumulation

Equipment List Hemochron® Signature Elite

Serial Number	Name	Location
SN	SE15004	ECLS
SN	SE15005	ECLS

Hemochron® Jr ACT-LR Reagent Storage and Stability

Reagent	Product number	Temperature	Stability
Hemochron® Jr ACT-LR test cuvettes	JACT-L	Fridge at 2 to 8°C	Until expiry
		Unopened at RT 12 weeks	12 Weeks
		Open at RT	24 hours
Abnormal *direct*CHECK® Whole Blood Quality Controls	DCJACT-A	Unopened at RT	4 weeks
		Fridge at 2 to 8°C	Until expiry
Normal *direct*CHECK® Whole Blood Quality Controls	DCJACT-N	Unopened at RT	4 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 day of patient testing (every thirty days if no patient testing performed).

Maintenance and QC Schedule for Hemochron® Signature Elite

Task	Frequency	Procedure
EQC	Every 8 Hours	Procedure 1.0 How to perform the Electronic Quality Control
Inspect and clean instrument as needed	Daily	Procedure 6.0 How to perform routine maintenance
Liquid QC Abnormal and Normal	• Every day of patient testing or every 30 days if no patient testing performed in the past 30 days. • With a new lot # of cuvettes • With a new shipment of cuvettes	Procedure: 2.0 How to perform the liquid QC on the Hemochron
Please send QA/Maintenance charts, Liquid QC charts to POCT laboratory or scan and email to POCTLAB@cw.bc.ca		

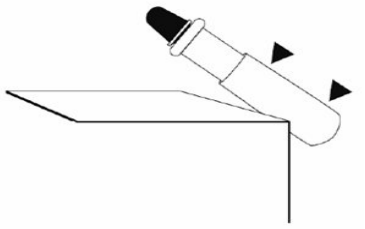
Procedure 1.0 How to perform the Electronic Quality Control (EQC) and battery check

	Action	Related Documents Title Number
	To Perform the Battery Check	
1.	The battery check must be performed before patient testing,	
2.	How to perform the battery check.	
3.	**Press and hold the "START" KEY to power ON.** 	
4.	Press "0" (zero) to display MAIN MENU.	
5.	Document the voltage of the battery.	
6.	Press "1". Battery status is displayed as OK, Low or BAD If the battery status is low it may need to be replaced soon. Contact supervisor to request battery to be ordered.	
7.	Press "CANCEL" twice.	
8.	The Hemochron when the battery is fully charged can be used unplugged for a minimum of 2 hours (49 tests at 150 sec per tests)	
9.	A fully drained battery will require an 8 hour charge.	
10.	11. Instrument requires a charge when "Charge Battery message is flashing on-screen.	
12.	When not in use please keep the hemochron plugged in.	
	To perform the EQC	
13.	Internal EQC provides two levels of electronic verification of instrument performance. EQC is to be performed at start up and every eight (8) hours while in use.	

	Action	Related Documents Title Number
14.	The Internal EQC will check the following parameters: 1. Normal level (30 ACT seconds), 2. Abnormal level of QC (500 ACT seconds) 3. Internal temperature	
15.	Press the "QC" key before a cuvette is inserted to get the QC status menu. 	
16.	Press "1-EQC". The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing.	
17.	When the test is completed, the results are displayed on the screen and written to the QC database within the instrument.	
18.	Document the EQC results on Appendix C ECLS EQC and Maint Form.	
19.	If the test fails, repeat the process.	
20.	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. 604 875 2345 ext 7521 POCTlab@cw.bc.ca	
	To review EQC results stored on DATA BASE	
21.	Press the DATA BASE key.	
22.	Select 5 key.	
23.	Scroll through the results to find the EQC by using the enter key.	
24.	To exit press CANCEL key.	
25.	If the user aborts the EQC, the test is not saved to the database..	
	Reminders	
26.	Please start a new sheet at the beginning of every month and whenever a new lot number of QC is started.	
27.	Every month please send the completed EQC/Maint and LQC Forms to POCT laboratory or scan and email to POCTLAB@cw.bc.ca.	

Procedure2.0: How to perform liquid QC on the Hemochron

	Action	Related Documents Title Number
1.	Two levels of liquid quality control, normal and abnormal range must be run once: 1. Every day of patient testing 2. Every 30 days if patient testing has not occurred for thirty days. 3. With every shipment of cuvettes. 4. With evert new lot # of cuvettes.	
2.	Write down the QC Lot# and the ranges provided on the appropriate forms. Appendix D ECLS LQC Form	
3.	Please send completed forms in step to POCT laboratory or scan and email to POCTLAB@cw.bc.ca.	
4.	Please start a new form (mentioned in step 2) in the following circumstances: • At beginning of every month • When a new shipment of cuvettes is started • When a new lot number of cuvettes is started • When a new lot number of QC is started	
	To Perform the Liquid QC (LQC)	
5.	Remove the *direct*CHECK vials, one normal level and one abnormal level, from the refrigerator and allow them to come to room temperature prior to testing. This will take about 60 minutes.	
6.	Remove two cuvettes from the refrigerator and allow them to come to room temperature. The foil pouch must be at room temperature before opening. This will take about 60 minutes.	
7.	Visually inspect each vial to ensure that the glass ampule inside the plastic vial is intact.	
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 hemochron will start warming the device while this is happening proceed to step 10.	
10.	Press “QC” soft key and select QC level (1-Normal or 2-Abnormal) to tag the sample.	
11.	The instrument will signal when ready with an audible beep, and display alternating messages: “Add Sample” and “Press Start”.	

	Action	Related Documents Title Number
	Please note that the instrument will: 1. Remain in the ready mode for five (5) minutes. 2. After 5 minutes will display “Start timeout”, indicating that the current cuvette must be discarded.	
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.	 As illustrated by the arrows, place thumbs on the protective sleeve To crush the vial perform the following steps: 1. Place the vial at the edge of the table top 2. Crush the middle of the vial 3. Twist the vial a quarter of a turn and crush the top 4. Twist the vial quarter of a turn and crush the bottom	
16.	Shake the vial vigorously for approximately 10 seconds. Does this by inverting the dropper vial (dropper tip down) end-to-end 10 times use a downward snapping motion of the wrist to ensure the control material flows to dropper tip.	
17.	Remove and retain the vial cap to discard the first drop of control material into to.	
18.	Squeeze the vial to discard the first drop of control material into the vial cap.	
19.	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.	

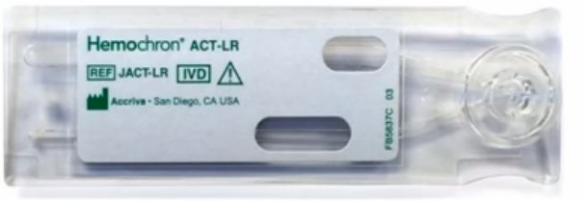
	Action	Related Documents Title Number
20.	Press the “START” key.	
21.	Dispose of the vial and vial cap according to department biohazard policy and retain the protective sleeve for reuse.	
22.	Document the result of the LQC on the Appendix D ECLS LQC Form. Please remember to include the following: 1. Lot number of the QC 2. Lot number of the Cuvette 3. Date and time. 4. Operator ID	
23.	In cases where LQC results are outside of an acceptable range, the cause may be one of the following: 1. Improper test or mixing technique 2. Expired or improperly stored QC Material 3. Expired or improperly stored cuvettes 4. Instrument or material temperature 5. Instrument malfunction.	
24.	Repeat the test using LQC material of the same lot number.	
25.	If this repeat does not fall within the expected range, address the above parameters again.	
26.	Obtain a cuvette from a different lot number and repeat the test using LQC material with the same lot number.	
27.	If this repeat test still does not fall within the expected range, do not use instrument for patient testing.	
28.	Notify the POCT technologist. 604 875 2345 ext 7521 POCTlab@cw.bc.ca	
	To review LQC results stored on DATA BASE	
1.	Press the DATA BASE key.	
2.	Select 5 key.	
3.	Scroll through the results to find the LQC by using the enter key.	
4.	To exit press CANCEL key.	
5.	If the user aborts the LQC, the test is not saved to the database or printed.	

	Action	Related Documents Title Number
	Reminders	
6.	Please start a new log sheet at the beginning of every month and whenever a new lot number of QC is started.	
7.	Monthly please send completed forms (Appendix D ECLS LQC Form) to POCT laboratory or scan and email to POCTLAB@cw.bc.ca.	

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.	Prior to patient testing confirm patient identification using two patient demographics. • Date of birth • MRN (medical record number) • PHN • Patient ID band • Government issued ID Use the patient identification protocol outlined by the department.	
2.	Please note 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) The LR-ACT should not be used with patients receiving the protease inhibitor Aprotinin, which is known to prolong Celite-based ACT measurements. Samples with hematocrits less than 20% or greater than 55% should not be tested and they may result in error messages.	
3.	Ensure the cuvette is at RT. If removing cuvette from the refrigerator, equilibration will take 60 minutes. 	

	Action	Related Documents Title Number
4.	Insert the cuvette into the cuvette opening.	
5.		
6.	The instrument will identify the test cuvette inserted and display the test.	
7.	This initiates the pre-warm/self-check mode.	
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.”	
11.	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.	
12.	Obtain a fresh whole blood sample (Please follow the process in your particular clinical program).	
13.	Immediately dispense one large drop of blood into the sample well of the test cuvette.	
14.	Fill the sample well from the bottom up with fresh whole blood.	
15.	A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top.	
16.	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.	
17.	When transferring blood into the sample well, do not force blood into the pin located on the center of the sample well.	
18.	Do not generate air bubbles in the sample well.	

	Action		Related Documents Title Number
19.	Press the “START” key.		
20.	Test completion will be indicated by a single beep.		
21.	Record results 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.	Remove the cuvette from the instrument and discard.		
Results and Follow-up Actions			
23.	**Out of Range-Lo**	Whole blood ACT-LR test results less than 68 seconds will result in an “Out-of-Range-Lo” error message. This may indicate excessive blood coagulation activation, that the sample has clotted prematurely or did not mix correctly in the cuvette. Bubbles may be present. The test should be repeated with a new cuvette to confirm the result.	**IFU**
24.	**Out of Range-Hi**	Whole blood ACT-LR test results greater than 400 seconds will result in an “Out-of-Range-Hi” error message. This may indicate excessive blood anticoagulation. The test should be repeated with a new cuvette to confirm the result.	
25.	**Unexpected ACT value**	Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be immediately repeated with a fresh cuvette. Contact the POCT technologist if instrument or reagent performance is suspected to be the cause.	

	Action		Related Documents Title Number
26.	**Reference Interval (normal ranges)**	Expected ACT-LR values for **non-heparinized** subjects: Normal adult donors 113-149 sec Adult ECMO patients 89 – 169 Data from 9 BCCH cath lab patients without anticoagulation gave ACT-LR values <149 sec	Package insert ACT-LR validation summary
27.	**Reference Interval (normal ranges)**	Expected ACT-LR values for **non-heparinized** subjects: Normal adult donors 113-149 sec Adult ECMO patients 89 – 169 Data from 9 BCCH cath lab patients without anticoagulation gave ACT-LR values <149 sec	Package insert ACT-LR validation summary

Procedure 5.0: Proficiency Testing

	Action	Related Documents Title Number
Proficiency testing is an external quality assurance scheme that requires POC users to test a set of blinded samples with the purpose of assessing testing accuracy. The results are evaluated by an external quality agency and compared with results from other labs and hospitals.		
1.	Twice a year the POCT team will contact the clinical user group to arrange for three proficiency testing samples to be analyzed by Hemochron users.	
2.	Please complete testing according to the accompanying instructions and return the results to POCT Lab by scan and email to POCTlab@cw.bc.ca	
3.	Results of proficiency test will be share with clinical users upon receipt of the evaluation scoring (1-3 months later). Clinical user groups are required to demonstrate acceptable PT performance to ensure ongoing function of the POC program.	

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 instrument as required.	
3.	Document on the QA/Maintenance log that hemochron has been inspected and cleaned as required. Appendix B.	
	To inspect and clean the cuvette opening	
4.	Remove residual dried blood or other foreign matter using water moistened cotton swabs.	
5.	Remove any residual water with a dry cotton swab.	
6.	If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water. Wipe the surface of the instrument with the solution using a dampened cloth. Take care not to get any disinfectant into the cuvette opening.	
7.	Wipe instrument with a water-dampened cloth to remove bleach from the plastic surfaces.	
8.	DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components.	
9.	Please send completed EQC/Maintenance log to POCT laboratory or scan and email to POCTLAB@cw.bc.ca.	

Procedure 7.0: Reminders

	Action	Related Documents Title Number
1.	POCT Lab will contact the department every month 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. 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.	

	Action	Related Documents Title Number
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.	
5.	Do not use excessive force when pressing the “START” key.	
6.	Do not allow the instrument to hit any hard surfaces or fall.	
7.	Do not expose the instrument to temperature 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. Successful performance of one level of QC	
3.	POCT Lab will work with the CNE to set up dates for the ongoing competency training.	

Procedure 9.0: Troubleshooting

	Action	Related Documents Title Number
1.	EQC failure. 1. Repeat EQC manually. 2. If step 1 does not resolve the issue then power the instrument off and then on again. then repeat EQC manually 3. If both steps 1 and 2 do not resolve the issue then call or email POCT Laboratory department. 604 875 2345 ext 7521 POCTlab@cw.bc.ca	
2.	Failures with the liquid QC 1. Review the QC preparation procedure. Incorrect or inadequate crushing, mixing and dispensing from the vial are frequently the cause of QC failures. Repeat testing with the liquid QC 2. The repeat from step 1 fails, repeat and have another operator perform the QC test. 3. Both steps 1 and 2 do not resolve the issue then call or email POCT Laboratory department. 604 875 2345 ext 7521 POCTlab@cw.bc.ca	Appendix E
3.	Issues with test results (for example, if results do not fit with the clinical picture: 1. Repeat testing immediately. 2. Consider alternate methods of assessing anticoagulation. Please note that 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) • Aprotinin • Extremely low or high hematocrit	

	Action	Related Documents Title Number
4.	Any other issues, concerns, complaints please contact: 604 875 2345 ext 7521 POCTlab@cw.bc.ca	

Procedure 10.0 Storage of Hemochron supplies

	Action			Related Documents Title Number
1.	Fridge temperature must be monitored daily. See Appendix F.			
2.	ECLS record the fridge temperature on the form provided. See Appendix F			
3.	ECLS Fridge Storage	White DANBY Fridge near transfusion med fridge T4 527		
	CATH Lab	TBD		
4.	**Reagent**	**Temperature**	**Stability**	
5.	Hemochron® Jr ACT-LR test cuvettes	Fridge at 2 to 8°C	Until expiry	Package insert
		Unopened at RT 12 weeks	12 Weeks	
6.	Abnormal *direct*CHECK® Whole Blood Quality Controls	Open at RT	24 hours	Package insert
		Unopened at RT	4 weeks	
7.	Normal *direct*CHECK® Whole Blood Quality Controls	Fridge at 2 to 8°C	Until expiry	Package insert
		Unopened at RT	4 weeks	
8.	If the fridge temperature is out of range then: Recheck in one hour. If still not within range contact the ECLS Team Leader. Contact POCTlab@cw.bc.ca			

	Action		Related Documents Title Number
9.	Department	Supplies ordered by	
	ECLS	QC and Cuvettes ordered by ECSL/perfusion. Stored in the DANBY white fridge near room T4 527	

Appendix A:
Hemochron HR ACT-LR Training & Competency Checklist

Name (Please Print):	Operator ID:	Department:	Trainer/s:	Date:

Operator demonstrates knowledge and/or competency in the following:	YES	NO
1. Battery / Power Supply. Instrument requires a charge when "Charge Battery message is flashing on-screen. When the battery is drained the instrument will need to be charged for 8 hr.		
2. Function of keys (alphanumeric and function)		
3. When and how to inspect and clean the hemochron. Document on QA/Maintenance log.		
4. Perform and evaluate acceptability of electronic Quality Control (Internal) – DAILY (Q 8 hr)		
5. Perform EQC every 8 hours (once per shift)		
6. Demonstrate how to perform EQC.		
7. Hemochron ACT Test Cuvette knowledge • Stored at room temperature (RT) stable for 3 months expiry from date kept at RT. • Stored 4°C stable until expiry date. • Must be brought to RT for 1 hour before testing.		
8. Storage and handling of Quality Control (QC) Solutions – Level1 & Level2 – • Stored at room temperature (RT) stable for 4 weeks from date kept at RT. • Stored 4°C stable until expiry date. • Must be brought to RT for 1 hour before testing.		
9. Testing Quality Control (QC) Solutions – Level1 & Level2 – • Every day of patient testing or every 30 days if no patient testing performed in the past 30 days. • With a new lot # of cuvettes • With a new shipment of cuvettes		
10. EQC/Maint, Liquid QC, Cuvette lot # must be documented on the forms provided.		
11. Cuvette(ACT-LR) & QC Storage		
12. Performs Daily Electronic Quality Control - documents on record form.		
13. Performs Liquid Quality Control L1 & L2 – day of patient testing and documents on record form.		

14. Review of QC results. Discussion of corrective action when QC is out of range. Documents any action taken on the Hemochron on the QC Record.		
15. Patient identification & sample application.		
16. Sample Collection – as per procedure – from the same syringe draw –& Hemochron ACT-LR. Documented time of collection needs to correlate on the Hemochron ACT-LR forms.		
17. Troubleshooting Guide – Error Codes (reverse of Quick Reference Guide)		
18. Employs standard precautions when performing the test. Appropriate disposal of test materials.		
19. Knows when and how to send QA/Maintenance charts, Liquid QC charts to POCT laboratory or scan and email to POCTLAB@cw.bc.ca.		

EQC Acceptance

Criteria:

Appendix C **ECLS Electronic Quality Control and Maintenance Form**

ECLS Electronic Quality Control and Maintenance Form (ECLS EQC and Maint Form)

Please start a new sheet at the beginning of every month.

Please scan and email completed from to poctlab@cw.bc.ca at the end of every month.

Location: ECLS

Date	Time	Operator ID	Cuvette lot In use this day	Instrument #: SE15004					Instrument #: SE15005					All QC Pass?
				Battery	Temp	Low	High	Inspect/clean	Battery	Temp	Low	High	Inspect clean	
Ddmmy	1400	1111	1212121	8.31	37	30	500	√		37	30	500	√	√

Battery	8 hour min charge required
Temp	37 °C ±1.0 °C
Low EQC	**29 - 31**
High EQC	**499 - 501**

EQC Acceptance

Criteria:

Appendix D HEMOCHRON SIGNATURE ELITE (ACT-LR) QUALITY CONTROL RECORD FORM Location ECLS SN SE15004 & SE15005

ECLS Liquid QC Form (ECLS LQC Form)

Please start a new sheet at the beginning of **every month, with a new lot of cuvettes, with a new lot of QC and a new shipment of cuvettes**

Please scan and email completed from to poctlab@cw.bc.ca at the end of every month. **Location: ECL**

Hemochron Jr ACT LR Cuvette Lot# Fridge Exp: Shipment Date	Level 1 QC Lot # Exp Acceptable QC Result Range:	Level 2 QC Lot # Exp Acceptable QC Result Range:	

Date	Time	QC Results SE15004	QC Pass	QC Results SE15005	QC Pass	QC Results SE15004	QC Pass	QC Results SE15005	QC Pass	Operator Initial/ID

Appendix E Hemochron direct Check LQC instructions by Accriva

Hemochron® SIGNATURE ELITE

Technical Support Tip

Management of directCheck Liquid Quality Control Material

Cuvette Type	directCheck Catalog Numbers
ACT+	DCJACT-N, DCJACT-A
ACT-LR	DCJLR-N, DCJLR-A
Whole Blood PT	DCJPT-N, DCJPT-A
Whole Blood APTT	DCJAPTT-N, DCJAPTT-A
Citrate PT and Citrate APTT	DCJCPT-N, DCJCPT-A and DCJCAPTT-A

Note: The entire process should take no longer than 15-18 seconds. Failure to follow this procedure may affect results.

Effective Crushing of the Vial

1. Insert the vial into the protective sleeve, and gently tap the vial on the table to ensure the glass ampule in the control vial is at the bottom.

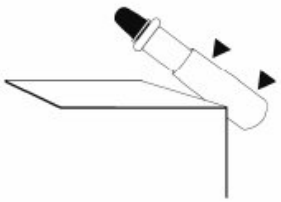
Note: Before crushing the vial, please make sure the cuvette is inserted in the instrument and the instrument display reads "Add Sample…"

2. As illustrated by the arrows, place thumbs on the protective sleeve.

   a. Crush middle of vial

   b. Twist vial quarter of turn and crush top

   c. Twist vial quarter of turn and crush bottom



Effective Mixing of the Vial

1. Shake the vial vigorously for approximately 10 seconds.

Applying the Sample to the Cuvette

1. Remove cap and discard the first drop into the cap.
2. Immediately dispense directCheck control into cuvette sample well and press "START"

For additional information such as storage and handling, please refer to the Package Insert.

If you require additional support, please contact Technical Support at 800-579-2255 (US toll-free), 858-263-2502 (outside the US) or email at techsupport@accriva.com.

Accriva diag

Appendix F Temperature Record Chart

Refrigerator Temperature Record Chart

Location	
POCT Device	Hemochron Supplies
Temperature Range	2 – 8 °C

Year												
	January		Febuary		March		April		May		June	
Day	Temp	Initial	Temp	Initial	Temp	Initial	Temp	Initial	Temp	Initial	Temp	Initial
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
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If temperature is not within range then monitor for the next hour if still not within range contact ECLS Team Leader and/or POCT lab at POCTlab@cw.bc.ca.
Contents can be moved to the laboratory or perfusion fridge.

Refrigerator Temperature Record Chart

Location	
POCT Device	Hemochron Supplies
Temperature Range	2 – 8 °C

	July		August		September		October		November		December	
Day	Temp	Initial	Temp	Initial	Temp	Initial	Temp	Initial	Temp	Initial	Temp	Initial
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References

Hemochron Signature Elite User Manual. Accessed online, February 2019; Archived version with the CW Lab: http://www.accriva.com/product-support/literature#filters:p-hemochron-signature-elite-whole-blood-microcoagulation-system,l-english,t-accriva-instrument-operator-manuals

Hemochron Jr ACT-LR Cuvette Package Insert. Accessed online, February 2019; Archived version with the CW Lab: http://www.accriva.com/product-support/literature#filters:p-hemochron-signature-elite-whole-blood-microcoagulation-system,l-english,t-accriva-package-inserts

directCheck Whole Blood Quality Control Package Insert. Acessed online, Feburary 2019; Archived version with the CW Lab: http://www.accriva.com/product-support/literature#filters:p-hemochron-signature-elite-whole-blood-microcoagulation-system,l-english,t-accriva-package-inserts

CW Laboratory Hemochron ACT-LR Validation, performed July-December 2018. Archived version with the CW Lab.

Revision Log

Version	Description of Change	Revision Date
1.0	Formatted for QMS upload	Feb 06 2019
1.1	Review SOP with CLee, HVallance and VBarakaukas	Feb 22 2019
