LR-ACT USING HEMOCHRON SIGNATURE ELITE

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Review Interval	2 Years

Changes from last version of this document

Transferred to new SHYPS template

General tidy up and reference updates.

Table of Contents

1 Purpose and Principle

The Hemochron Signature Elite Point of Care Testing (POCT) instrument has been approved for use within the Vascular Imaging Unit (VIU) and Coronary Care Unit (CCU) at York Teaching Hospitals NHS Foundation Trust to monitor heparin therapy associated with Percutaneous Vascular Intervention (PCI). The instrument utilizes a mechanical endpoint detection mechanism to detect clot formation occurring within a disposable single-use cuvette to measure the activated clotting time at the low range (ACT-LR).

The operator inserts a cuvette for the test into the instrument; the cuvette warms to 37°C ± 1.0°C. Following whole blood sample introduction to the cuvette, the instrument precisely measures and transfers 15µL of blood into the cuvette test channel (the remainder of the blood sample is automatically drawn into the waste channel of the cuvette). Sample / reagent mixing, and test initiation are performed automatically, and the test sample is moved back and forth at a predetermined rate within the test channel and monitored for clot formation.

The clot detection mechanism utilises LED optical detectors that are aligned with the test channel of the cuvette. The speed at which the blood sample moves between the detectors is measured and 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 threshold rate. Electronic optical detection of a fibrin clot in the blood sample automatically terminates the test. The instrument's digital timer measures the elapsed time between the start of the test and the clot formation. At the end of the test, the instrument displays the ACT-LR time in seconds.

2 Patient Preparation & Sample Requirements

One drop of fresh whole blood or citrated whole blood can be used. Fresh whole blood is used routinely. Blood must not be collected from a heparinised line or indwelling heparin lock.

3 Tasks, Responsibilities and Authorisations

The system is for use by any healthcare professional that has had the required training, records of training are stored on AEGIS POC middleware, accessed by POCT staff.

Tasks	Responsible	Authorised
LR-ACT testing on Signature Elite	**Trained Healthcare professionals**	**Signed off by POCT team or ACT link trainer signed off by POCT**

4 Equipment

Hemochron Signature Elite Analyser

LR-ACT cassettes

DirectCheck Quality Control - Normal and Abnormal

All test cuvettes and quality controls are ordered by Vascular Imaging Unit Ext 6165

Werfen Hemochron- Signiture Elite analyser

Werfen

712 The Quadrant, Cavendish Avenue

Birchwood, Warrington

Cheshire WA3 6DE

UK

Tel: +44 (0)1925 810 141

5 Chemicals and Reagents

Hemochron Jr. ACT-LR test cuvettes.

DirectCheck Quality Control - Normal and Abnormal

Store cuvettes and liquid control material at 2-8°C until the manufacturer's stated expiration date. Cuvettes may be stored at room temperature (18-30°C) for 12 weeks and control at room temperature for 4 weeks but must be marked with new expiry date (12 or 4 weeks from date of removal – do not exceed manufacturer's stated expiration date) when removed from the fridge. Cuvettes and controls should be at room temperature prior to use. Opened cuvettes or reconstituted QC material should be used immediately.

6 Risk Assessment

For full risk assessment see PC/RA/YS-14 Risk Assessment for the Hemochron Signature Elite

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

COSHH and Risk Assessment

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

No calibration by the user is required for the Hemochron Signature Elite®. The Hemochron is calibrated at the manufacturing facility to test and verify all functions. In addition, the Hemochron is self-calibrating; all instrument functions are continuously monitored and verified by the software when a test is performed.

8 Quality Control

Electronic QC Check (EQC) provides a two-level electronic verification of instrument performance plus a verification of the temperature. If one result fails, the test will stop and all results will be recorded as “failed”. It is required every 8 hours of patient testing, and the Hemochron will lock out operation if it is not performed (if the meter is kept switched on). EQC will be performed automatically if the Hemochron is plugged into the AC/DC power module and is turned on. Routinely, however, the meter is not kept turned on, so EQC should be performed manually on a daily basis. To perform an EQC manually press the QC button followed by the 1 key. When the test is completed, results will be displayed and written to the QC database. Press the CANCEL button to exit the screen. All results of the EQC test should be recorded on the daily QC chart kept with the Hemochron.

Liquid QC Checks

Normal and abnormal liquid quality controls (LQC) are performed:

- With each new shipment / lot of cuvettes
- Every 30 days
- When a shift in clinical results is suspected

Procedure:

- Remove the ACT-LR test cuvettes and the DirectCheck vials (normal and abnormal control material) from the refrigerator; to come to room temperature; this may take up to 60 minutes.
- Check expiry date on all reagents and visually inspect the control vials to ensure that the glass ampoule is intact.
- After reagents have reached room temperature, insert an ACT-LR cuvette into the cuvette slot on the side of the Hemochron.
- If LQC is due, select the QC being run (QC Normal / QC Abnormal). If LQC is not ‘due’ but is being run, press the QC key and select QC Normal / QC Abnormal. If the QC key / level of QC is not selected, the Hemochron will identify the test as a patient test.
- When LQC is due, the Hemochron will lock-out operation.
- The Hemochron will signal when ready with an audible tone (beep) and the display will indicate “ADD SAMPLE” and “PRESS START.”
- Reconstitute the QC dropper vial (begin with the normal level):
- Remove the top of the plastic seal from the QC vial.
- Insert the QC vial into the white protective sleeve.
- Holding the vial upright, tap the QC vial on the bench top to settle the inner glass ampoule to the bottom of the vial.
- Crush the inner glass ampoule by either bending the vial over the edge of a bench top or by crushing the vial between two fingers.
- Immediately repeat the crushing action one to two additional times to ensure complete breakage of the glass ampoule.
- Quickly invert the dropper vial end to end

- While inverting the vial (dropper tip down), use a downward snapping motion of the wrist to ensure the control material flows to the dropper tip.
- Remove and retain the vial cap.
- Squeeze the vial to discard the first drop of control material into the vial cap.
- 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 central sample well, push it over into the outer sample well.
- Press the START key on the Hemochron.
- Recap the control vial and remove the vial from the protective sleeve. Discard the vial and vial cap in a sharps bin; retain the protective sleeve for reuse.
- Wait for a single beep signalling the end of the test. (Two beeps indicate a fault condition).
- The result is displayed as the Celite equivalent clotting time. Document the QC result. Note: The Hemochron Signature Elite® may be programmed for the result to display as “Pass” or “Fail”.
- Compare the result with the acceptable range published on the DirectCheck package insert in use.
- Repeat the procedure using the abnormal liquid QC material.

Invalid Quality Control result(s)

When QC results are outside the acceptable range, verify the following immediately:

- Ensure that controls and cuvettes have not expired. If expired, discard and repeat the tests with new reagents / cuvettes. Ensure proper Hemochron temperature; perform the instrument temperature verification procedure (EQC).
- Ensure proper technique. The timing from crushing the vial to pressing the START key is critica
- Ensure adequate cuvette sample volume.
- Check the control material for the presence of clots. If present, repeat the procedure using freshly prepared samples of control material.
- If the procedure is repeated with new reagents / cuvettes and the QC results continue to be outside the acceptable range, DISCONTINUE USE OF THE INSTRUMENT AND REPORT THE FAULT - The Hemochron / cuvettes must NOT be used for patient testing until all control values are within the acceptable range. Document all faults and corrective actions.

9 External Quality Assurance (EQA)

External Quality Assurance samples are received every 4 months from NEQAS and due to sample preparation are analysed by the POCT team. Results should then be returned to the schme prior to the closing deadline.

10 Procedural Steps

- Identify the patient by asking them to confirm their name and Date of Birth.
- Turn on the Hemochron by pressing the start button
- Insert the ACT-LR cuvette into the cuvette opening on the side of the Hemochron – check the expiry and integrity of the cuvette pouch. The Hemochron will identify the cuvette inserted and display the test name. The Self-Check will be initiated.
- Enter or scan the patient’s ID at the PID prompt NHS Number where possible. If scanned, the PID will be automatically stored. If manually entering the PID,

press ENTER until stored is displayed on the screen – CHECK THE DETAILS ARE ACCURATE

- The Hemochron will signal when ready with an audible tone (beep) and the display will indicate “ADD SAMPLE” and “PRESS START.” The Hemochron 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 new cuvette placed in the cuvette opening.

Collect Sample

- Clean the 3-way tap.
- Draw off 5 – 10mls of blood and discard.
- When the machine says, “ADD SAMPLE” Immediately dispense one drop of blood into the sample well of the cuvette. Fill the sample well from the bottom up with whole blood. A sufficient quantity of blood must be added directly to the centre of the sample well to fill it flush to the top. Should a large drop of blood extend over the top of the centre sample well, creating a dome, push it over into the outer sample well. Note: When transferring blood into the sample well:
- Do NOT force blood into the pin located on the centre of the sample well.
- Do NOT generate air bubbles in the sample well.
- Press the START key on the Hemochron. Test completion will be indicated by a single beep. The ACT-LR result is automatically converted to a reference Celite ACT result and displayed as the Celite equivalent result in seconds.
- Enter a note(s) if applicable. Up to 2 operator selectable notes can be added to the patient record for each test; the note will be recorded in the final record. A cuvette must be in the Hemochron to enter a note.
- To enter a note, press the NOTE key. Type the number of the predefined note(s) or press the NOTE key repeatedly until the desired note is displayed.
- Press ENTER. Press CANCEL to return to normal operation.
- Write the result into the patient’s notes, noting the date, time and name of the person performing the test, as well as the results and their units (seconds).
- Remove the test cuvette and discard appropriately.

The meter should be cleaned daily and as required throughout the day using a clinell wipe or a cloth moistened with mild soapy water, 70% isopropyl alcohol or 0.625% sodium hypochlorite, in particular the cuvette opening.

11 Reporting of Results

- All results must be documented in the patient’s notes
- A result that exceeds “400 seconds” and reads “out of range Hi” is reported as “greater than 400" if the result is expected.
- If any result is inconsistent with patient therapy, repeat the test.
- If the result is “out of range Lo”, repeat the test with a new sample and new cuvette.

All results are stored on Aegis POC Middleware.

12 Reference Intervals

Expected values are dependent upon heparin dosage / procedure.

Unexpected results (i.e. inconsistent with the patient's clinical state) should be repeated or confirmed with additional testing

For further guidance see the Hemochron Whole Blood Microcoagulation Systems Low Range Activated Clotting Time (ACT-LR) Package Insert, International Technidyne Corporation, NJ, Current Version.

13 Performance Characteristics and Limitations

The Hemochron Signature Elite® test results are affected by poor technique during blood collection and the transfer of blood to the sample well. The quality of the blood specimen may be affected by:

Contamination e.g. heparin line, diluted sample

Foaming of the sample (air bubbles)

Haemolysis

Clotted or partially clotted blood

Unsuspected anticoagulation

Presence of a lupus anticoagulant

The Hemochron 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 patients receiving aprotinin.

Samples with a haematocrit less than 20% or greater than 55% are not recommended for testing; the optical density is outside the level of detection of the Hemochron Signature Elite®. Where haematocrit may be out of this range, refer a FBC to the laboratory to confirm.

As with all diagnostic tests, the Hemochron Signature Elite® 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.

Quoted precision Data

Within Day	Mean (sec)	SD(sec)	CV %
Normal	208	14	6.7
Abnormal	299	11	3.8

Day to Day	Normal			Abnormal		
	Mean	SD	CV	Mean	SD	CV
Day 1	202	7.9	3.9	292	17.6	6.0
Day2	217	18.7	8.6	300	1.5	0.5
Day 3	214	11.7	5.5	303	702	2.4

Total	211	13.4	6.4	298	10.8	3.6

haematocrit may be out of this range, refer a FBC to the laboratory to confirm.

14 Related Forms/Templates and Documents

PC/RA/YS-14 Risk Assessment for the Hemochron Signature Elite

PC/VV/YS-4 Verification of ACT-LR on the Hemochron Signature Elite

15 References

Hemochron Signature Elite® Operator's Manual, International Technidyne Corporation, NJ, HX1101 09/06.

Hemochron Whole Blood Microcoagulation Systems Low Range Activated Clotting Time (ACT-LR) Package Insert, International Technidyne Corporation , NJ, Current Version.

Direct Check Whole Blood Control for Hemochron Microcoagulation Systems Package Insert, International Technidyne Corporation , NJ, Current Version.

Hemochron Low Range Activated Clotting Time (ACT-LR) Document WI.POC.003, ANMED Health Laboratory Services, Anderson, SC, 05/06.

Werfen Website www.werfen.com

Evaluation Document located in Q-Pulse PC/VV/YS-4 Verification of ACT-LR on the Hemochron Signature Elite.