Keywords: EQC, hemochron, LQC, point of care, QC, quality control

I. PURPOSE
This procedure provides instructions for performing Internal Electronic Quality Control (EQC) that includes a Temperature check (TQC) and Liquid Quality Control (LQC) on the HEMOCHRON Signature Elite for software version V2.01.

II. MATERIALS

<table>
<thead>
<tr>
<th>Supplies</th>
<th>Equipment</th>
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<tr>
<td>• Vinyl or Nitrile disposable gloves</td>
<td>• HEMOCHRON® Signature Elite</td>
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<tr>
<td>• JHMI approved biohazard waste container</td>
<td>• AC/DC Power Module (ITC Part No. HX1025)</td>
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<tr>
<td></td>
<td>• LQC-Normal</td>
</tr>
<tr>
<td></td>
<td>• LQC-Abnormal</td>
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<td></td>
<td>• Communication cable</td>
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III. REAGENTS AND STORAGE

Bring all reagents to room temperature at least one hour prior to testing. Users will obtain cuvettes from units.

<table>
<thead>
<tr>
<th>ITC ACT-LR and ACT+ CUVETTES</th>
<th>Direct Check ACT LR and ACT+ LQC</th>
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<tbody>
<tr>
<td>Store at 2-8 °C (36-46 °F)</td>
<td>Store at 2-8 °C (36-46 °F)</td>
</tr>
<tr>
<td>Good for 12 weeks at 15-30 °C (59-86 °F)</td>
<td>Good for 4 weeks at 15-30 °C (59-86 °F)</td>
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</table>

IV. SPECIMEN

Direct Check Normal and Abnormal Quality Control vials.

V. SAFETY PRECAUTIONS

Follow Standard Precautions and CDC handwashing guidelines when performing this test.

VI. FREQUENCY

1. Internal Electronic System Verification will be run every 8 hours of patient testing. If the meter has been configured for "Auto EQC" and is plugged in, the EQC will ensue every 8 hours automatically.
2. Liquid Quality Control is run weekly for ACT-LR and ACT Plus.

VII. QC PROCEDURE

Internal Electronic System Verification

1. Display the QC status by pressing the QC key before a cuvette is inserted.
2. Press ‘1’. The test chamber warms to temperature and the EQC begins. The results are displayed while the test is progressing.
3. When the test is completed, the results are displayed on the screen and written to the QC database.
4. Notes:
   1. Internal EQC will check two levels of QC and the temperature, and it will store each result.
   2. If one level of EQC fails, the test will stop and record all results as failed. If the user aborts the internal EQC, the test is not saved to the database.
   3. If repeat EQC fails, discontinue testing. Contact the Point-of-Care Testing Office at 5-2645 for assistance.
   4. Expected results are as follows:
      1. Meters configured for ACT-LR: Temperature = 37.0 ° +/- 0.1, Level 1 = 30 +/- 1, Level 2 = 300 +/- 1
      2. Meters configured for ACT +: Temperature = 37.0 ° +/- 0.1, Level 1 = 30 +/- 1, Level 2 = 500 +/- 1

Liquid Quality Control

1. Enter or scan operator ID, cuvette lot # and LQC lot # as prompted.
2. To run LQC when it is not required, press the QC key. To run mandatory LQC, the message “LQC expired” is displayed.
3. Select 1-QN (Normal LQC) or 2-QN (Abnormal LQC).
4. Instrument displays “Priming Pump…”, “Warming…”
5. The instrument will signal when ready with an audible beep, and display the messages, “Add Sample” and “Press Start”.
6. Remove the plastic seal from the top of the Direct Check vial.
7. Insert the vial into the white protective sleeve.
8. Holding the vial upright, tap it on the table-top to settle the inner glass ampule at the bottom of the vial.
9. Crush the inner glass ampule by either bending the vial over the edge of the table-top or by crushing the vial between two fingers.
10. Immediately repeat this crushing action one or more times.
11. Quickly invert the dropper vial end to end 10 times.
12. Remove and retain the vial cap
13. Remove the white protective sleeve and make sure all control material flows to the dropper end.
14. Squeeze the vial and discard the first drop into the vial cap.
15. Immediately fill up the cuvette sample well flush to the top. Push any excess sample over into the outer sample well.
16. Press Start
17. Dispose the vial and vial cap appropriately.
18. Once done, the meter will beep and display “QC Passed” or “QC Failed”.
19. Remove the used cuvette and discard it in an appropriate biohazard waste container.
20. Run the next QC level. Repeat steps 1-20
21. Instrument is now ready for patient testing.

**LQC Corrective Action**

If results fall outside the acceptable range:

1. Repeat test
2. If the repeat falls within the acceptable range, continue with patient testing.
3. If the repeat falls outside the acceptable range, i.e. two consecutive failures for the same QC level, the meter will be locked from further testing. Contact the POCT office, 5-2645 for assistance and to unlock the meter.
4. The POCT office will work with the operator running QC to determine if the failure is due to technique or a meter malfunction. The POCT office will complete the Hemochron QC Lockout Evaluation form, Appendix A and add a note to the QC records in QML as to the outcome of the evaluation.
5. If the technique is determined to be the problem and the QC rerun is successful, the meter can be returned to the unit for patient testing.
6. If the cause for the QC failure is undeterminable, a 10-day validation will ensue where EQC and LQC are run for a period of 10 days. The validation is best done by the POCC and a loaner issued to the unit.
7. Upon completion of 10 consecutive successful EQC/LQC runs and acceptable CV% (#15%), the meter may be returned to the unit.
8. If the meter continues to fail LQC, the POCT office will contact the manufacturer’s technical support for troubleshooting assistance.

**LQC/EQC Validation**

In the event of two consecutive LQC failures as described above and an operator error has been ruled out, an LQC/EQC validation must be initiated for a period of 10 days. LQC will be run in conjunction with EQC every 8 hours of meter use.

Other reasons for initiating LQC/EQC Validation include:

- On initial use of the meter or after service
- Failure of proficiency testing
• Unacceptable correlation results
• Patient results are inconsistent with the patient's clinical picture.

VIII. REFERENCES

IX. SPONSOR AND DEVELOPER
   Sponsor:
   Pathology Performance Improvement

   Developer:
   Point of Care Testing Office

   Review Cycle: Two (2) years

X. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
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<tbody>
<tr>
<td>William Clarke</td>
<td>04/05/2023</td>
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<tr>
<td>Doctor of Philosophy</td>
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