


Werfen GEM Hemochron 100 analyser Quality Control Guide	Q Pulse Reference Number POC-PINS-23	 MAKING EVERY TEST MATTER
Version Number 1.0	Author Cecilia Anghelescu	

Werfen GEM Hemochron 100 analyser Quality Control Guide

Two-Level Quality Control (QC)

Two levels of QC must be performed every 8 hours of operation. This requirement can be met by conducting EQC or LQC testing. LQC testing should be initiated directly after EQC has passed.



Electronic Quality Control (EQC): Manual

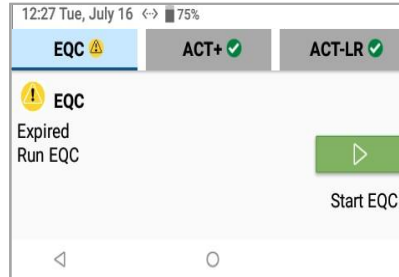
(Optional if Auto-EQC not configured)

1. Select QC

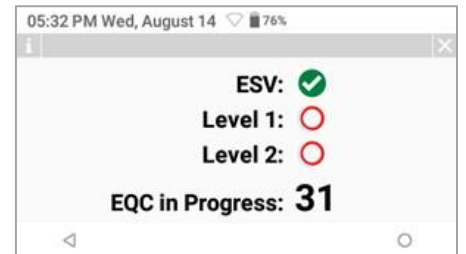


1. Tap screen and then  (1).

2. Start EQC

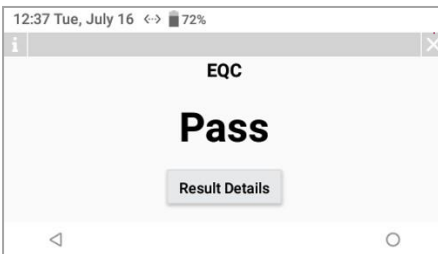




2. Select **Start EQC**  (2).





Three instrument-validation phases will be initiated. EQC test result will be displayed.

3. Results Display



Select  (3) to return to home screen,  to view test result details.

Note: Test result will be stored in Database  and sent to Laboratory Information System (LIS), if auto-send is on.

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Liquid Quality Control (LQC) (direct CHECK)

Note: Remove appropriate quality control dropper vials (direct CHECK) from refrigerator and allow them to come to room temperature. This could require up to 60 minutes.

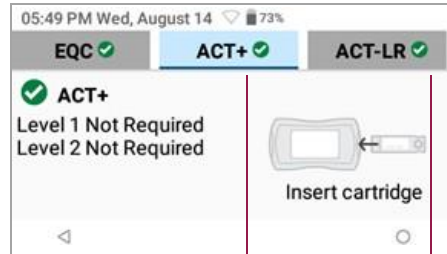
1. Select QC



1.

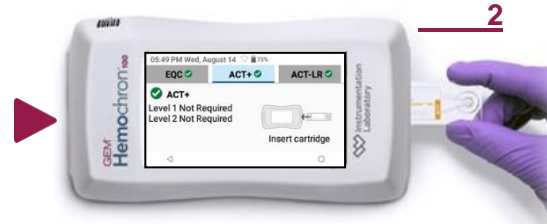
On **Home** screen, select  (1).

2. Select LQC and Insert cartridge





2a

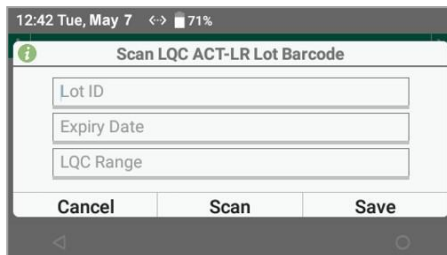
2b



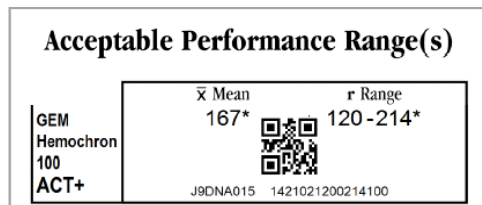
2

Select appropriate tab ( (2a) or  (2b)) and insert (appropriate) cartridge for LQC (ACT+ or ACT-LR) (2).

3. Scan LQC barcode (Performance-Range Card)

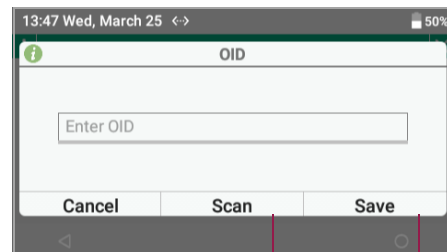


3. 4. 5.



Select **Scan** (3) and scan compatible barcode on Acceptable Performance-Range card, provided on package insert for respective LQC (4). Select **Save** (5).

4. Enter OID (optional)



6

7

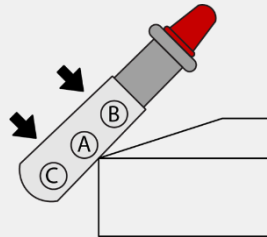
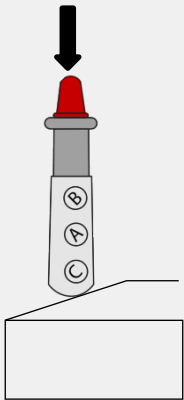
If prompted, enter, or scan the Operator ID. Select **Scan** (6) and then **Save** (7). Wait while instrument warms and prepares cartridge.

5. Prepare LQC (See next page)

5. Prepare LQC

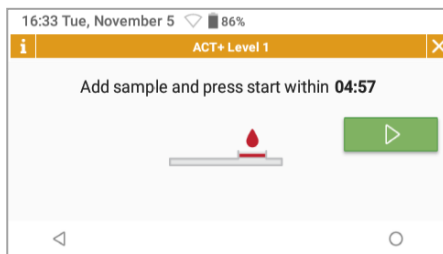
Note: Ensure vial is in protective sleeve

1. Remove plastic, shrink-wrapped label. Hold vial upright and gently tap bottom of ampule on tabletop to set inner glass ampule on vial bottom.
2. Break vial by placing thumbs on protective sleeve. While continuing to hold vial upright, use edge of table to crush inner glass ampule as follows:
 1. Crush middle (A)
 2. Twist a quarter turn and crush top (B)
 3. Twist another quarter turn and crush bottom (C)
3. With dropper tip facing down, shake vial with a downward snapping motion **10 times**.
4. Tap vial cap on tabletop. Remove vial cap and discard first drop into cap. **IMMEDIATELY** dispense second drop into cartridge and select **Start**.




directCHECK steps 2–4 must be completed in ≤ 18 seconds

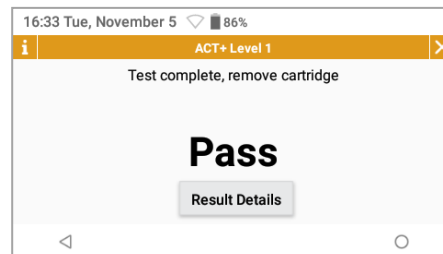
6. Add LQC Sample



8.


Add direct CHECK sample to cartridge sample well. Select  (8). Instrument will count up and display result after clotting detected.

7. Results Display



9.

When LQC test result is displayed, remove cartridge, and dispose of direct CHECK material and cartridge in biohazardous waste container, according to institutional guidelines.

Optional: Select  (9) to review test information.