Haemonetics TEG6s Internal Quality Control Test Quick Guide

TEG®6s Cartridge Reagent Quality Control (QC) Guide

Performing Reagent QC on Citrated Patient Cartridge

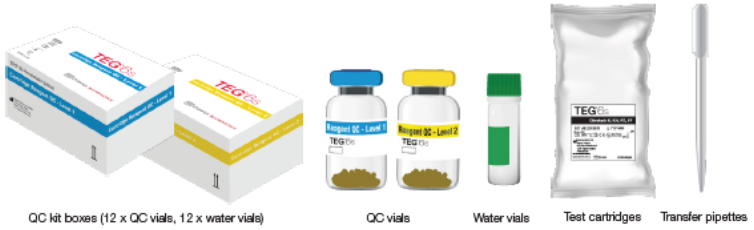
Quality controls may be used with the ctirated patient cartridge to verify cartridge reagent performance. This may be performed to verify appropriate handling and storage conditions upon receipt of new cartridges or whenever cartridges are exposed to adverse environmental conditions.This can supplement the laboratory's development of its own Individualised Quality Control Plan (IQCP) based on ISO 14971:2019 and the lab's risk analysis.
Haemonetics offers two levels of QC reagent kits:

- Cartridge Reagent QC - Level 1 (07-664)
- Cartridge Reagent QC - Level 2 (07-665)

Cartridge Reagent QC Material

Prepare a Level 1 and a Level 2 Reagent QC.

For each you will need a vial of the QC material and a vial of water from the reagent QC kit, a transfer pipette and citrated cartridge to be tested.



Cartridge Reagent QC Preparation

To run cartridge reagent QC, you need to prepare the QC material by reconstituting it with water. Take care with the sample preparation to ensure accurate results. Preparation is the same for both Level 1 and Level 2 QC materials.

1. Room temperature

- Remove the citrated patient cartridge pouch from the refrigerator and set aside.
- Remove the QC vial and water vial.
- Allow the vials to sit for approximately 10 minutes to come to room temperature.

2. Add water

- Tap QC vial to ensure all material settles at the bottom then carefully remove stopper.
- Tap water vial on counter, remove cap and pour into QC vial. **Ensure all water goes into QC vial.**

3. Shake

Immediately re-insert QC stopper. Holding the stopper in place, vigorously shake the QC vial for 15 seconds.

4. Rest

Let stand for 5 minutes at room temperature.

5. Shake

Vigorously shake the QC vial again, for 15 seconds.

6. Rest

- Let stand for 5 minutes at room temperature.
- Ensure QC material is clear and has no visible particles.
- Repeat vigorous shaking if needed and stand a further 5 minutes.
- Test within 2 hours of reconstitution.

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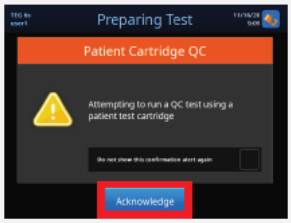
Cartridge Reagent QC Testing

Now that the QC material(s) are prepared, you are ready to run QC in a patient cartridge. This section outlines the general procedure for running QC material in a patient cartridge on the TEG® 6s analyzer. The following steps are the same for both Level 1 and Level 2 QC materials.

1. Select "New QC"

Touch "New QC" to begin.

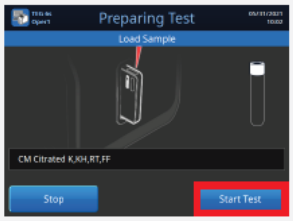


2. Insert cartridge

- When prompted, insert the cartridge with the barcode on the left.
- Upon detecting a patient cartridge the analyzer may ask you to confirm the cartridge type.
- Touch "Acknowledge" to proceed with Cartridge Reagent QC.

3. Select QC Level

- Select the QC that you wish to run, and then select "Next".
- If desired enter information in the Test Information screen and then select "Next".

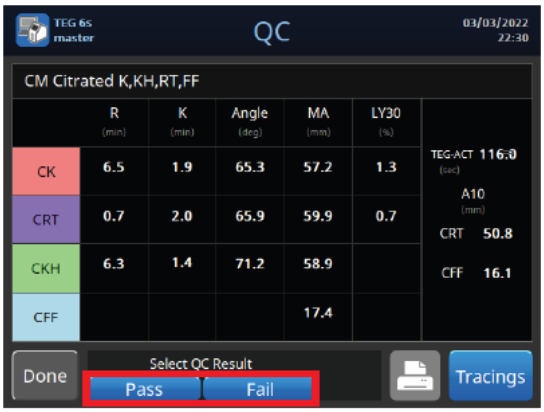


4. Dispense QC sample

- Using supplied transfer pipette, dispense the appropriate QC material up to or above the fill line on the cartridge port.
- Touch "Start Test" to commence.

Cartridge Reagent QC Results

QC Results Global Haemostais (07-601)



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QC Reference Ranges

Cartridge Reagent QC - Level 1	TEG-ACT (sec)	R (min)	K (min)	Angle (deg)	A10 (mm)	MA (mm)	LY30 %
CK – L1		4.6 - 13.1	0.8 - 4.1	58 - 81		55 - 73	0.0 - 0.0
CRT – L1	78 - 154	NA	0.3 - 0.8	77 - 86	NA	55 - 73	0.0 - 0.0
CKH – L1		3.6 - 8.6	0.8 - 2.1	58 - 81		55 - 73	
CFF – L1					NA	55 - 73	

Reference ranges L1-QC (07-664) from kit insert.

Cartridge Reagent QC - Level 2	TEG-ACT (sec)	R (min)	K (min)	Angle (deg)	A10 (mm)	MA (mm)	LY30 %
CK – L2		1.0 - 1.7	0.7 - 1.4	61 - 81		22 - 34	79 - 95
CRT – L2	78 - 144	NA	0.7 - 1.3	73 - 81	NA	22 - 34	79 - 95
CKH – L2		1.0 - 1.7	0.7 - 1.4	61 - 81		22 - 34	
CFF – L2					NA	22 - 34	

Reference ranges L2-QC (07-665) from kit insert.

- Two QC Result buttons (Pass and Fail), will display at the bottom of the screen when the test is completed.
- Compare the results against the manufacturer's reference ranges outlined in the QC kit insert.
- Select "Pass" if all results are within range or "Fail" if any result is outside of range.
- A confirmation message will appear, select "Acknowledge".
- Reagent performance is verified if all parameters fall within the reference ranges shown in the applicable table.
- The ability of the cartridge to neutralise heparin can be confirmed if the difference between CK and CKH – R on the Global Haemostasis cartridge is > 1.2 minutes.