

QUALITY CONTROL

For use with the RNA Medical, Inc.

QC 900

**RNA MEDICAL QC900
HEMATOCRIT CONTROL
KIT LOT # 63944
LEVEL 1 LOT 63914
LEVEL 2 LOT 64014
EXP. 02/18**

For use with CC and H3 Cartridges

The attached bar codes are to be used with your IRMA TRUpoint scanner*

For Software 3.0.11 and higher.

Please refer to the package insert for specific information about this control material.

Introduction & Intended Use

With the IRMA TRUpoint Blood Analysis System, Quality Control can be performed through two methods: electronic and liquid controls.

It is important to follow RNA's recommended procedures for storage and equilibration of the control material prior to analysis on the IRMA TRUpoint Analyzer.

Instructions for Use

Equilibrate ampules at room temperature (18-25°C) for at least 8 hours before use.

1. Hold the ampule by its tip and shake it vigorously for 10 seconds. Tap the liquid back into the base of the ampule and set down until ready to use.
2. Enter User ID (optional) at the display prompt on the IRMA TRUpoint Analyzer.
3. Initiate the Quality Control Test Sequence.
4. Open the foil pouch and remove the cartridge.
5. Remove the protective tape from the cartridge.
6. Insert the cartridge into the analyzer.
7. Verify or enter the cartridge information at the display prompt.

8. Select the control from the list of established controls.
9. After calibration is complete, carefully snap open the control ampule.

To avoid cuts, protect your fingers with tissue or gloves, or use an ampule breaker.
10. Slowly draw ~1 mL of control into a 1 mL syringe, or nearly the entire ampule contents into a 2 or 3 mL syringe using an 18 – 20 gauge needle. Place the needle opening below the liquid surface when drawing to minimize air contamination. When done, remove the needle from the syringe.
11. Do not attempt to invert the syringe or expel bubbles from the syringe after drawing up the control solution.
12. Remove the luer cap from the cartridge and firmly attach the syringe to the luer port. Inject all but the last syringe contents into the cartridge, taking care not to inject air bubbles into the sample path and press "test" to initiate the analysis.

Expected Analyzer Performance

The values on the Expected Values Chart are based on the results of multiple sample analysis. Samples were introduced using a 1 cc syringe, with an 18 gauge needle, after cartridge equilibration at 22°C (72°F) for a minimum of 8 hours.

Use the expected values for each parameter as a guide in evaluating performance. Since performance is subject to sample temperature and environmental barometric pressure, LifeHealth recommends that each institution establish its own expected values and acceptable limits. The mean values established at your institution should fall within the expected ranges.

References

1. Moran RF. Assessment of quality control of blood gas/pH analyzer performance. Respiratory Care 1981 (June).

Expected Values Chart

Level 1:

HCT (%)	20.5 - 26.5
---------	-------------

Level 2:

HCT (%)	43.6 – 49.6
---------	-------------

***NOTE: These values are for CC and H3 cartridges when used with the IRMA.**

The IRMA TRUPOINT quality control sheets with bar codes are designed to be used with the IRMA TRUPOINT scanner. If you are unable to scan the bar codes after printing please manually input the ranges accordingly. For questions please contact LifeHealth technical support services at 855-762-8378 or 651-638-1000.

QUALITY CONTROL
For use with the RNA Medical, Inc.
QC 900

Level 1 – Lot 63914

A



B



C



The IRMA TRUPOINT quality control sheets with bar codes are designed to be used with the IRMA TRUPOINT scanner. If you are unable to scan the bar codes after printing please manually input the ranges accordingly. For questions please contact LifeHealth technical support services at 855-762-8378 or 651-638-1000.

QUALITY CONTROL
For use with the RNA Medical, Inc.
QC 900

Level 2 – Lot 64014

A



B



C



The IRMA TRUPOINT quality control sheets with bar codes are designed to be used with the IRMA TRUPOINT scanner. If you are unable to scan the bar codes after printing please manually input the ranges accordingly. For questions please contact LifeHealth technical support services at 855-762-8378 or 651-638-1000.