

# QUALITY CONTROL

For use with the RNA Medical, Inc.

## QC 823 Blood Gas /Electrolyte/Metabolyte/BUN Control

### For use with H4 Cartridges

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

**RNA MEDICAL QC 823**  
**KIT LOT# 715989**  
**LEVEL 1 LOT 71529**  
**LEVEL 2 LOT 71628**  
**LEVEL 3 LOT 71729**  
**EXP. 01/20**

For Software 7.0.0 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 at the top and bottom (with forefinger and thumb) and shake it for 10 seconds to mix the solution. Tap the ampule to restore the liquid to the bottom 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, use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers and open the ampule by snapping off the tip at the score.

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 Cal 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.<sup>1</sup> 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:

Na+ (mM)	107.6 – 117.6
K+ (mM)	1.60 – 2.60
Cl- (mM)	68.3 – 78.3
BUN (mg/dL)	7 - 13

##### Level 2:

Na+ (mM)	126.4 – 136.4
K+ (mM)	3.95 – 4.95
Cl- (mM)	84.9 – 94.9
BUN (mg/dL)	27 - 37

##### Level 3:






Na+ (mM)	151.9 – 161.9
K+ (mM)	5.65 – 6.65
Cl- (mM)	109.5 – 119.5
BUN (mg/dL)	45 - 61

**\*NOTE: These values are for H4 cartridges when used with the IRMA TRUPOINT Analyzer only.**

\* 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 and services at 1-855-762-8378 or +1 (651)638-1000.

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**Level 1 – Lot 71529**

- A** 
- B** 
- C** 
- D** 
- E** 

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**Level 2 – Lot 71628**

- A** 
- B** 
- C** 
- D** 
- E** 

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**Level 3 – Lot 71729**

**A** 

**B** 

**C** 

**D** 

**E** 

**F** 

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