IRMA TRUPOINT

LIFEHEALTH DIAGNOSTICS FOR BETTER HEALTH

QUALITY CONTROL

For use with the RNA Medical, Inc.

QC 623 Blood Gas/Electrolyte Controls

RNA MEDICAL QC 623
KIT LOT N/A
LEVEL 1 LOT 60225
LEVEL 2 LOT 60324
LEVEL 3 LOT 60424
EXP. 02/20

For use with CC, BG, 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 **TRU**POINT 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 **TRU**POINT 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 **TRU**POINT 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 the control sample into a 1 mL or 3 mL syringe using an 18-20 gauge needle.
11. Do not attempt to invert the syringe or expel bubbles from the syringe after drawing up the control solution.
12. Remove the needle, inject the control into the cartridge using a minimum of 0.8 mL of the control sample in a 1.0 mL syringe or a minimum of 1.5 mL of the control sample in a 3.0 mL syringe 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.

Notes and Limitations

In establishing the values shown on the Expected Values Chart, samples were analyzed after equilibration at 22°C (72°F) for a minimum of 8 hours. The pCO_2 and pO_2 values vary inversely with temperature by approximately one percent per degree Celsius. Refer to Temperature Correction for information to adjust pCO_2 and pO_2 ranges for operating outside of the 21-23°C temperature range.

In establishing the values shown in Expected Values, samples are analyzed at approximately 760 mmHg. The pO_2 values decrease by approximately 2.3% per 100 mmHg and the pCO_2 values decrease by 1% at the same atmospheric conditions.[4]

Temperature Correction

It has been reported the pCO_2 and pO_2 results were inversely affected by temperature.[2,3] If your laboratory routinely operates in the 18-20°C (64-68°F) or 24-25°C (75-77°F) range or experiences seasonal variations in temperature, you can adjust the ranges to account for these temperature effects, as shown below.

For example, if your room temperature is typically 24-25°C and the range in the Expected Values Chart for pO2, Level 3 is 20.3-23.0, you can adjust the range as follows:

Lower limit: 20.3 - 0.51 = 19.79
Upper limit: 23.0 - 0.51 = 22.49
Adjusted range = 19.79 - 22.49

Temperature Correction for pCO_2 and pO_2

	Level	18-20°C	21-23°C	24-25°C
pCO_2	1	+ .29	no change	- .24
pO2	1	+ .33	no change	- .28
pO_2	2	+ .47	no change	- .40
pO_2	3	+ .61	no change	- .51

References

1. Moran RF. Assessment of quality control of blood gas/pH analyzer performance. Respiratory Care 1981 (June).
2. Maas AHV. Evaluation of ampouled tonometered buffer solutions as a quality-control system for pH, pCO_2 and pO_2 measurement. Clin Chem 1977; 23(9): 1718-25.
3. Battino R, Rettich TR, Tominaga T. The solubility of oxygen and ozone in liquids. J of Phys Chem Ref Data 1983; 12(2): 163-178.
4. Burnett RW and Itano M. An interlaboratory study of blood-gas analysis: Dependence of pO_2 and pCO_2 results on atmospheric pressure. Clin Chem 1989; 35(8): 1779-1781.

Expected Values Chart

Level 1:

pH	**7.132 – 7.192**
pCO_2 (kPa)	**8.73 – 10.87**
pO_2 (kPa)	**7.59 – 10.25**
Na+ (mmol/L)	**109.8 – 119.8**
K+ (mmol/L)	**1.52 – 2.52**
iCa (mmol/L)	**1.35 – 1.55**

Level 2:

pH	**7.403 – 7.463**
pCO_2 (kPa)	**5.23 – 6.56**
pO_2 (kPa)	**12.97 – 15.64**
Na+ (mmol/L)	**129.8 – 139.8**
K+ (mmol/L)	**3.82 – 4.82**
iCa (mmol/L)	**0.99 – 1.19**

Level 3:

pH	**7.657 – 7.717**
pCO_2 (kPa)	**1.96 – 3.29**
pO_2 (kPa)	**18.56 – 21.22**
Na+ (mmol/L)	**159.3 – 169.3**
K+ (mmol/L)	**5.69 – 6.69**
iCa (mmol/L)	**0.40 – 0.60**

***The IRMA TRU**POINT **quality control sheets with bar codes are designed to be used with the IRMA TRU**POINT **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.**

IRMA TRUPOINT

LIFEHEALTH DIAGNOSTICS FOR BETTER HEALTH

QUALITY CONTROL

For use with the RNA Medical, Inc.

QC 623 Blood Gas/Electrolyte Controls

Level 1 – Lot 60225

A

B

C

D

E

F

G

H

***The IRMA TRU**POINT **quality control sheets with bar codes are designed to be used with the IRMA TRU**POINT **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.**

IRMA TRUPOINT

LIFEHEALTH DIAGNOSTICS FOR BETTER HEALTH

QUALITY CONTROL

For use with the RNA Medical, Inc.

QC 623 Blood Gas/Electrolyte Controls

Level 2 – Lot 60324

A

B

C

D

E

F

G

H

***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.**

IRMA TRUPOINT

LIFEHEALTH DIAGNOSTICS FOR BETTER HEALTH

QUALITY CONTROL

For use with the RNA Medical, Inc.

QC 623 Blood Gas/Electrolyte Controls

Level 3 – Lot 60424

A

B

C

D

E

F

G

H

***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.**