


## Blood Gas • Electrolyte • Metabolite Control

**LOT** 94114

 2012-12

**REF** QC 823-0

**IVD**

### INTENDED USE

RNA Medical® Brand QC 823 Range Blood Gas • Electrolyte • Metabolite Control is an assayed quality control material used for monitoring the performance of blood gas, electrolyte, and metabolite instrumentation for the analytes and analyzers listed on the Expected Values Chart.

### PRODUCT DESCRIPTION

QC 823 Range is provided in two (2) levels. The analyte values in each level are higher or lower than those found in traditional control levels, extending the range of values for which analyzer performance is monitored. QC 823 Range is packaged in sealed glass ampuls, each containing 2.5 mL of solution. Ampuls are packaged thirty (30) per box.

#### Active Ingredients:

QC 823 Range is a buffered aqueous solution containing electrolytes (Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>), glucose, and lactate. It has been equilibrated with specific levels of CO<sub>2</sub>, O<sub>2</sub>, and N<sub>2</sub>. This control contains no preservatives and no human or biological materials.

### STORAGE

The expiration date stated on the QC 823 Range packaging is for product stored refrigerated (2-8 °C). The product may also be stored at room temperature (up to 25 °C) for nine (9) months, provided the labeled expiration date is not exceeded. Avoid freezing and temperatures greater than 30 °C.

### DIRECTIONS FOR USE

The control should be brought to a temperature of 20-25 °C before use (see instructions regarding Expected Values). Allow at least four (4) hours for the ampuls to equilibrate to this temperature prior to testing.

For pH/blood gas values, the control should be analyzed immediately after opening. For electrolyte, glucose, and lactate measurements, QC 823 Range is stable for up to one (1) hour after opening.

Before use, hold the ampul at the top and bottom (with forefinger and thumb) and shake for 10 seconds to mix the solution. Tap the ampul to restore the liquid to the bottom. Use gauze, tissue, gloves, or an appropriate ampul opener to protect fingers from cuts and open the ampul by snapping off the tip at the score. Immediately introduce the liquid from the ampul to the analyzer, following the instrument manufacturer's instructions for sampling a control material. Use direct aspiration, syringe transfer, or capillary mode techniques.

### EXPECTED VALUES

The values for each control analyte on the enclosed Expected Values Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range and mean value of this range for ampuls that are at 25 °C when tested. (Note: pO<sub>2</sub> values will vary inversely by about one percent (1%) per degree Celsius that the temperature of the ampul varies from 25 °C.)

The Expected Values are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the Expected Value range shown on the chart.

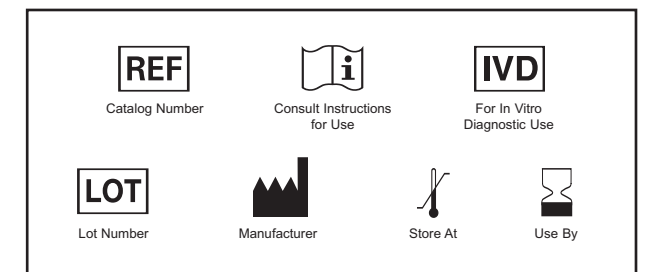
### STATISTICAL SUPPORT

RNA Medical PeerQC®, available at [www.RNAMedical.com](http://www.RNAMedical.com), provides monthly statistical reports for tracking and review of analyzer performance as well as lot number specific peer group data. This service is available at no charge to RNA Medical customers. Please contact RNA Medical or visit our website for information about utilizing PeerQC for this product.

### LIMITATIONS

- QC 823 Range is sensitive to many instrument related factors that would affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions that would affect the testing of blood.
- This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

RNA Medical is a registered trademark and PeerQC is a registered service mark of Bionostics, Inc.



### INSTRUMENT MANUFACTURERS

- Instrumentation Laboratory, Lexington, MA
- Medica Corporation, Bedford, MA
- Nova Biomedical, Waltham, MA
- OPTI Medical, Roswell, GA
- Radiometer America, Westlake, OH
- Roche Diagnostics, Indianapolis, IN
- Siemens Healthcare Diagnostics, Inc., Tarrytown, NY
- YSI, Yellow Springs, OH



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# QC 823 Range Blood Gas • Electrolyte • Metabolite Control

Level 0

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## Expected Values Chart

Manufacturer / Analyzer	pH		pCO <sub>2</sub> mmHg		pO <sub>2</sub> mmHg		Ca <sup>++</sup> mmol/L		Na <sup>+</sup> mmol/L		K <sup>+</sup> mmol/L		Cl <sup>-</sup> mmol/L		Mg <sup>++</sup> mmol/L		Glucose mg/dL		Lactate mmol/L		H <sup>+</sup> nmol/L		pCO <sub>2</sub> kPa		pO <sub>2</sub> kPa		Glucose mmol/L			
	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range		
<b>IL</b>																														
1300 Series	6.84	6.81 - 6.87	87	75 - 99	29	14 - 44																144.5	154.9 - 134.9	11.6	10.0 - 13.2	3.9	1.9 - 5.9			
BG3	6.84	6.81 - 6.87	92	80 - 104	24	9 - 39																144.5	154.9 - 134.9	12.3	10.7 - 13.9	3.2	1.2 - 5.2			
BGE	6.84	6.81 - 6.87	92	80 - 104	25	10 - 40	3.02	2.52 - 3.52	86	81 - 91	11.7	9.2 - 14.2										144.5	154.9 - 134.9	12.3	10.7 - 13.9	3.3	1.3 - 5.3			
1600 Series	6.84	6.81 - 6.87	95	83 - 107	26	11 - 41	2.97	2.47 - 3.47	87	82 - 92	12.2	9.7 - 14.7		DNA <sup>2</sup>								144.5	154.9 - 134.9	12.7	11.1 - 14.3	3.5	1.5 - 5.5			
Synthesis Series	6.85	6.82 - 6.88	91	79 - 103	19	4 - 34	2.87	2.37 - 3.37	85	80 - 90	11.8	9.3 - 14.3	68	63 - 73			393	343 - 443				141.3	151.4 - 131.8	12.1	10.5 - 13.7	2.5	0.5 - 4.5	21.8	19.0 - 24.6	
GEM Premier	ORL <sup>1</sup>		ORL <sup>1</sup>		36	21 - 51	3.47	2.97 - 3.97	ORL <sup>1</sup>		ORL <sup>1</sup>											ORL <sup>1</sup>		ORL <sup>1</sup>		4.8	2.8 - 6.8			
GEM Premier 3000	ORL <sup>1</sup>		95	83 - 107	37	22 - 52	3.19	2.69 - 3.69	ORL <sup>1</sup>		11.7	9.2 - 14.2										ORL <sup>1</sup>		12.7	11.1 - 14.3	4.9	2.9 - 6.9			
<b>Medica</b>																														
EasyBloodGas	DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>																									
EasyStat	DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>																	
<b>Nova</b>																														
Stat Profile 1-9	6.89	6.86 - 6.92	90	78 - 102	24	9 - 39	2.91	2.41 - 3.41	88	83 - 93	11.7	9.2 - 14.2	71	66 - 76			443	393 - 493	15.6	12.1 - 19.1	128.8	138.0 - 120.2	12.0	10.4 - 13.6	3.2	1.2 - 5.2	24.6	21.8 - 27.4		
Stat Profile 10	6.86	6.83 - 6.89	92	80 - 104	22	7 - 37			88	83 - 93	11.9	9.4 - 14.4	71	66 - 76			453	403 - 503	15.6	12.1 - 19.1	138.0	147.9 - 128.8	12.3	10.7 - 13.9	2.9	0.9 - 4.9	25.1	22.4 - 27.9		
Stat Profile Ultra	6.90	6.87 - 6.93	87	75 - 99	22	7 - 37	2.91	2.41 - 3.41	88	83 - 93	11.9	9.4 - 14.4	71	66 - 76	DNA <sup>2</sup>		453	403 - 503	15.6	12.1 - 19.1	125.9	134.9 - 117.5	11.6	10.0 - 13.2	2.9	0.9 - 4.9	25.1	22.4 - 27.9		
<b>OPTI Medical</b>																														
OPTI CCA	DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>									DNA <sup>2</sup>								
OPTI R	DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>																	
OPTI LION	DNA <sup>2</sup>						DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>		DNA <sup>2</sup>																	
<b>Radiometer</b>																														
ABL 3, 30	6.85	6.82 - 6.88	90	78 - 102	31	16 - 46																141.3	151.4 - 131.8	12.0	10.4 - 13.6	4.1	2.1 - 6.1			
ABL 300 Series	6.85	6.82 - 6.88	90	78 - 102	30	15 - 45																141.3	151.4 - 131.8	12.0	10.4 - 13.6	4.0	2.0 - 6.0			
ABL 4	6.84	6.81 - 6.87	90	78 - 102	33	18 - 48					11.4	8.9 - 13.9										144.5	154.9 - 134.9	12.0	10.4 - 13.6	4.4	2.4 - 6.4			
ABL 5	6.84	6.81 - 6.87	92	80 - 104	22	7 - 37																144.5	154.9 - 134.9	12.3	10.7 - 13.9	2.9	0.9 - 4.9			
ABL 50, 500 Series	6.84	6.81 - 6.87	91	79 - 103	37	22 - 52	3.08	2.58 - 3.58	87	82 - 92	11.3	8.8 - 13.8	66	61 - 71								144.5	154.9 - 134.9	12.1	10.5 - 13.7	4.9	2.9 - 6.9			
ABL 600 Series	6.84	6.81 - 6.87	91	79 - 103	37	22 - 52	3.08	2.58 - 3.58	87	82 - 92	11.3	8.8 - 13.8	66	61 - 71			413	363 - 463	14.9	11.4 - 18.4	144.5	154.9 - 134.9	12.1	10.5 - 13.7	4.9	2.9 - 6.9	22.9	20.1 - 25.7		
ABL 700 Series	6.84	6.81 - 6.87	89	77 - 101	40	25 - 55	3.12	2.62 - 3.62	87	82 - 92	11.3	8.8 - 13.8	67	62 - 72			416	366 - 466	14.9	11.4 - 18.4	144.5	154.9 - 134.9	11.9	10.3 - 13.5	5.3	3.3 - 7.3	23.1	20.3 - 25.9		
ABL 800 Series	6.84	6.81 - 6.87	89	77 - 101	40	25 - 55	3.12	2.62 - 3.62	87	82 - 92	11.3	8.8 - 13.8	67	62 - 72			416	366 - 466	14.9	11.4 - 18.4	144.5	154.9 - 134.9	11.9	10.3 - 13.5	5.3	3.3 - 7.3	23.1	20.3 - 25.9		
ICA, KNA 1							3.00	2.50 - 3.50	86	81 - 91	11.3	8.8 - 13.8																		
EML Series							3.08	2.58 - 3.58	87	82 - 92	11.3	8.8 - 13.8	66	61 - 71			413	363 - 463	14.9	11.4 - 18.4										
<b>Roche</b>																														
AVL Compact Series	6.83	6.80 - 6.86	91	79 - 103	37	22 - 52																147.9	158.5 - 138.0	12.1	10.5 - 13.7	4.9	2.9 - 6.9			
OMNI 1-9	6.88	6.85 - 6.91	91	79 - 103	22	7 - 37	2.91	2.41 - 3.41	88	83 - 93	11.5	9.0 - 14.0	74	69 - 79			421	371 - 471	16.2	12.7 - 19.7	131.8	141.3 - 123.0	12.1	10.5 - 13.7	2.9	0.9 - 4.9	23.4	20.6 - 26.1		
<b>Siemens (Bayer)</b>																														
238	6.84	6.81 - 6.87	102	90 - 114	36	21 - 51																144.5	154.9 - 134.9	13.6	12.0 - 15.2	4.8	2.8 - 6.8			
248	6.85	6.82 - 6.88	102	90 - 114	22	7 - 37																141.3	151.4 - 131.8	13.6	12.0 - 15.2	2.9	0.9 - 4.9			
400 Series	6.78	6.74 - 6.82	104	90 - 118	44	28 - 60	2.83	2.33 - 3.33	ORL <sup>1</sup>		11.0	8.5 - 13.5	ORL <sup>1</sup>				451	401 - 501				166.0	182.0 - 151.4	13.9	12.0 - 15.7	5.9	3.7 - 8.0	25.0	22.3 - 27.8	
800 Series	6.85	6.82 - 6.88	95	83 - 107	26	11 - 41	2.94	2.44 - 3.44	83	78 - 88	11.5	9.0 - 14.0	67	62 - 72			443	393 - 493	14.3	10.8 - 17.8	141.3	151.4 - 131.8	12.7	11.1 - 14.3	3.5	1.5 - 5.5	24.6	21.8 - 27.4		
600 Series	6.84	6.81 - 6.87					3.22	2.72 - 3.72	85	80 - 90	ORL <sup>1</sup>		71	66 - 76								144.5	154.9 - 134.9							
1200 Series	6.85	6.82 - 6.88	99	87 - 111	36	21 - 51	3.11	2.61 - 3.61	81	76 - 86	11.7	9.2 - 14.2	67	62 - 72			403	353 - 453	14.4	10.9 - 17.9	141.3	151.4 - 131.8	13.2	11.6 - 14.8	4.8	2.8 - 6.8	22.4	19.6 - 25.1		
<b>YSI</b>																														
2300 Stat Plus																						433	383 - 483	16.4	12.9 - 19.9			24.0	21.3 - 26.8	

Footnotes:  
 1. ORL - Outside (Analyzer's) Reportable Limits  
 2. DNA - Data Not Available at Time of Printing

