


Blood Gas • Electrolyte • Metabolite Control

LOT 24218

 2015-01

REF QC 823-5

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⁺, K⁺, Cl⁻, Ca⁺⁺, Mg⁺⁺), glucose, and lactate. It has been equilibrated with specific levels of CO₂, O₂, and N₂. 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: pO₂ 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.

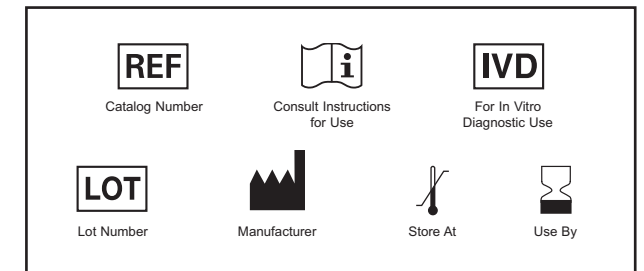
STATISTICAL SUPPORT

RNA Medical PeerQC®, available at www.RNAMedical.com, 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

1. 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.
2. 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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Level 5

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Expected Values Chart

Manufacturer / Analyzer	pH		pCO ₂ mmHg		pO ₂ mmHg		Ca ⁺⁺ mmol/L		Na ⁺ mmol/L		K ⁺ mmol/L		Cl ⁻ mmol/L		Mg ⁺⁺ mmol/L		Glucose mg/dL		Lactate mmol/L		H ⁺ nmol/L		pCO ₂ kPa		pO ₂ 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	Mean	Range		
IL																																
1600 Series	7.78	7.74 - 7.82	12	8 - 16	477	417 - 537	0.23	0.13 - 0.33	168	163 - 173	1.4	0.9 - 1.9										16.6	18.2 - 15.1	1.6	1.1 - 2.1	63.6	55.6 - 71.6					
Synthesis Series	7.80	7.76 - 7.84	14	10 - 18	482	422 - 542	0.20	0.10 - 0.30	167	162 - 172	1.8	1.3 - 2.3	129	124 - 134			0	0 - 5				15.8	17.4 - 14.5	1.9	1.3 - 2.4	64.3	56.3 - 72.2	0.0	0.0 - 0.3			
GEM Premier 3000 Series	ORL ¹		12	8 - 16	453	393 - 513	0.12	0.02 - 0.22	178	173 - 183	1.4	0.9 - 1.9					DNA ²		DNA ²		ORL ¹		1.6	1.1 - 2.1	60.4	52.4 - 68.4	DNA ²					
GEM Premier 4000	7.86	7.82 - 7.90	13	9 - 17	490	430 - 550	0.13	0.03 - 0.23	167	162 - 172	1.4	0.9 - 1.9	135	130 - 140			ORL ¹		10.2	7.7 - 12.7		13.8	15.1 - 12.6	1.7	1.2 - 2.3	65.3	57.3 - 73.3	ORL ¹				
Medica																																
EasyBloodGas	DNA ²		DNA ²		DNA ²																	DNA ²		DNA ²		DNA ²						
EasyStat	DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²									DNA ²		DNA ²		DNA ²						
Nova																																
CCX	7.79	7.75 - 7.83	14	10 - 18	481	421 - 541	0.23	0.13 - 0.33	171	166 - 176	1.6	1.1 - 2.1	134	129 - 139	DNA ²		DNA ²		11.7	9.2 - 14.2		16.2	17.8 - 14.8	1.9	1.3 - 2.4	64.1	56.1 - 72.1	DNA ²				
pHOx	7.79	7.75 - 7.83	14	10 - 18	497	437 - 557																16.2	17.8 - 14.8	1.9	1.3 - 2.4	66.3	58.3 - 74.2					
pHOx Plus	7.78	7.74 - 7.82	14	10 - 18	532	472 - 592	DNA ²		168	163 - 173	1.6	1.1 - 2.1	124	119 - 129			DNA ²		DNA ²			16.6	18.2 - 15.1	1.9	1.3 - 2.4	70.9	62.9 - 78.9	DNA ²				
Stat Profile 1-10	7.79	7.75 - 7.83	13	9 - 17	477	417 - 537	0.20	0.10 - 0.30	170	165 - 175	1.8	1.3 - 2.3	132	127 - 137			0	0 - 5	10.9	8.4 - 13.4		16.2	17.8 - 14.8	1.7	1.2 - 2.3	63.6	55.6 - 71.6	0.0	0.0 - 0.3			
Stat Profile Ultra	7.81	7.77 - 7.85	13	9 - 17	479	419 - 539	0.20	0.10 - 0.30	171	166 - 176	1.6	1.1 - 2.1	132	127 - 137	DNA ²		0	0 - 5	10.9	8.4 - 13.4		15.5	17.0 - 14.1	1.7	1.2 - 2.3	63.9	55.9 - 71.8	0.0	0.0 - 0.3			
OPTI Medical																																
OPTI CCA	ORL ¹		13	10 - 16	469	409 - 529	ORL ¹		ORL ¹		1.4	0.9 - 1.9	139	133 - 145			ORL ¹					ORL ¹		1.7	1.3 - 2.1	62.5	54.5 - 70.5	ORL ¹				
OPTI R	ORL ¹		12	9 - 15	469	409 - 529	ORL ¹		DNA ²		DNA ²											ORL ¹		1.6	1.2 - 2.0	62.5	54.5 - 70.5					
OPTI LION	DNA ²						DNA ²		DNA ²		DNA ²		DNA ²									DNA ²										
Radiometer																																
ABL 5	7.78	7.74 - 7.82	13	9 - 17	507	447 - 567																16.6	18.2 - 15.1	1.7	1.2 - 2.3	67.6	59.6 - 75.6					
ABL 50, 500 Series	7.79	7.75 - 7.83	13	9 - 17	462	402 - 522	0.22	0.12 - 0.32	167	162 - 172	1.5	1.0 - 2.0	127	122 - 132								16.2	17.8 - 14.8	1.7	1.2 - 2.3	61.6	53.6 - 69.6					
ABL 600 Series	7.79	7.75 - 7.83	13	9 - 17	462	402 - 522	0.22	0.12 - 0.32	167	162 - 172	1.6	1.1 - 2.1	127	122 - 132			0	0 - 5	10.2	7.7 - 12.7		16.2	17.8 - 14.8	1.7	1.2 - 2.3	61.6	53.6 - 69.6	0.0	0.0 - 0.3			
ABL 700 Series	7.79	7.75 - 7.83	13	9 - 17	457	397 - 517	0.25	0.15 - 0.35	168	163 - 173	1.7	1.2 - 2.2	130	125 - 135			0	0 - 5	10.5	8.0 - 13.0		16.2	17.8 - 14.8	1.7	1.2 - 2.3	60.9	52.9 - 68.9	0.0	0.0 - 0.3			
ABL 77, 80 Series	DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²									DNA ²		DNA ²		DNA ²						
ABL 800 Series	7.79	7.75 - 7.83	13	9 - 17	447	387 - 507	0.28	0.18 - 0.38	168	163 - 173	1.7	1.2 - 2.2	130	125 - 135			0	0 - 5	10.5	8.0 - 13.0		16.2	17.8 - 14.8	1.7	1.2 - 2.3	59.6	51.6 - 67.6	0.0	0.0 - 0.3			
NPT 7	DNA ²		DNA ²		DNA ²																	DNA ²		DNA ²		DNA ²						
Roche																																
AVL Compact Series	7.79	7.75 - 7.83	13	9 - 17	486	426 - 546																16.2	17.8 - 14.8	1.7	1.2 - 2.3	64.8	56.8 - 72.8					
Cobas b 221	7.74	7.70 - 7.78	13	9 - 17	467	407 - 527	DNA ²		DNA ²		DNA ²		DNA ²									DNA ²		DNA ²		18.2	20.0 - 16.6	1.7	1.2 - 2.3	62.3	54.3 - 70.2	DNA ²
OMNI 1-9	7.75	7.71 - 7.79	14	10 - 18	442	382 - 502	0.17	0.07 - 0.27	172	167 - 177	1.6	1.1 - 2.1	133	128 - 138			ORL ¹		11.5	9.0 - 14.0		17.8	19.5 - 16.2	1.9	1.3 - 2.4	58.9	50.9 - 66.9	ORL ¹				
Siemens (Bayer)																																
238	7.80	7.76 - 7.84	13	9 - 17	477	417 - 537																15.8	17.4 - 14.5	1.7	1.2 - 2.3	63.6	55.6 - 71.6					
248	7.80	7.76 - 7.84	13	9 - 17	477	417 - 537																15.8	17.4 - 14.5	1.7	1.2 - 2.3	63.6	55.6 - 71.6					
400 Series	ORL ¹		ORL ¹		466	406 - 526	ORL ¹		172	162 - 182	1.5	1.0 - 2.0	132	122 - 142			ORL ¹					ORL ¹		ORL ¹		62.1	54.1 - 70.1	ORL ¹				
800 Series	7.82	7.78 - 7.86	13	9 - 17	463	403 - 523	0.23	0.13 - 0.33	170	165 - 175	1.4	0.9 - 1.9	129	124 - 134			ORL ¹		9.6	7.1 - 12.1		15.1	16.6 - 13.8	1.7	1.2 - 2.3	61.7	53.7 - 69.7	ORL ¹				
600 Series	7.80	7.76 - 7.84					0.20	0.10 - 0.30	168	163 - 173	1.5	1.0 - 2.0	131	126 - 136																		
1200 Series	7.82	7.78 - 7.86	12	8 - 16	475	415 - 535	ORL ¹		165	160 - 170	1.4	0.9 - 1.9	131	126 - 136			ORL ¹		11.1	8.6 - 13.6		15.1	16.6 - 13.8	1.6	1.1 - 2.1	63.3	55.3 - 71.3	ORL ¹				
YSI																																
2300 Stat Plus																						0	0 - 5	11.7	9.2 - 14.2					0.0	0.0 - 0.3	

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