


Blood Gas • Electrolyte • Metabolite Control

LOT 74112

 Exp.: 2010-02

REF QC 823-0

IVD For *In Vitro* Diagnostic Use

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.

RNA Medical provides monthly statistical reports for tracking and review of analyzer performance as well as lot number specific peer group data. Please contact RNA Medical for information about this service.








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 of Bionostics, Inc. The products described herein are covered by one or more of the following U.S. Patents and their foreign counterparts: 5,558,985; 5,320,965; 5,304,491; 5,045,529; 5,013,666; 4,945,062.

INSTRUMENT MANUFACTURERS

- Bayer HealthCare LLC, East Walpole, MA
- Instrumentation Laboratory, Lexington, MA
- Nova Biomedical, Waltham, MA
- Radiometer America, Westlake, OH
- Roche Diagnostics, Indianapolis, IN
- YSI, Yellow Springs, OH


 Catalog Number	 Consult Instructions for Use	 For In Vitro Diagnostic Use
 Lot Number	 Manufactured For	 Store At
		 Use By


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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 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		
Bayer																														
238	6.84	6.81 - 6.87	101	89 - 113	35	20 - 50															144.5	154.9 - 134.9	13.5	11.9 - 15.1	4.7	2.7 - 6.7				
248	6.85	6.82 - 6.88	101	89 - 113	21	6 - 36															141.3	151.4 - 131.8	13.5	11.9 - 15.1	2.8	0.8 - 4.8				
278, 280	6.85	6.82 - 6.88	98	86 - 110	26	11 - 41															141.3	151.4 - 131.8	13.1	11.5 - 14.7	3.5	1.5 - 5.5				
288	6.85	6.82 - 6.88	98	86 - 110	26	11 - 41	3.27	2.77 - 3.77	82	77 - 87	12.3	9.8 - 14.8	71	66 - 76							141.3	151.4 - 131.8	13.1	11.5 - 14.7	3.5	1.5 - 5.5				
840, 845, 850, 855, 860, 865	6.85	6.82 - 6.88	94	82 - 106	25	10 - 40	3.09	2.59 - 3.59	83	78 - 88	11.9	9.4 - 14.4	67	62 - 72			442	392 - 492	14.1	10.6 - 17.6	141.3	151.4 - 131.8	12.5	10.9 - 14.1	3.3	1.3 - 5.3	24.5	21.8 - 27.3		
634	6.84	6.81 - 6.87					3.37	2.87 - 3.87																						
614, 644									83	78 - 88	ORL ¹		71	66 - 76																
IL																														
1304, 1306, 1312	6.84	6.81 - 6.87	86	74 - 98	28	13 - 43															144.5	154.9 - 134.9	11.5	9.9 - 13.1	3.7	1.7 - 5.7				
BG3	6.84	6.81 - 6.87	91	79 - 103	23	8 - 38															144.5	154.9 - 134.9	12.1	10.5 - 13.7	3.1	1.1 - 5.1				
BGE	6.84	6.81 - 6.87	91	79 - 103	24	9 - 39	3.17	2.67 - 3.67	84	79 - 89	11.6	9.1 - 14.1									144.5	154.9 - 134.9	12.1	10.5 - 13.7	3.2	1.2 - 5.2				
1610, 1620, 1630, 1640, 1650	6.84	6.81 - 6.87	94	82 - 106	25	10 - 40	3.12	2.62 - 3.62	85	80 - 90	12.1	9.6 - 14.6	DNA ²								144.5	154.9 - 134.9	12.5	10.9 - 14.1	3.3	1.3 - 5.3				
Synthesis 10, 15, 20, 25, 30, 35	6.85	6.82 - 6.88	90	78 - 102	18	3 - 33	3.02	2.52 - 3.52	83	78 - 88	11.7	9.2 - 14.2	68	63 - 73			392	342 - 442			141.3	151.4 - 131.8	12.0	10.4 - 13.6	2.4	0.4 - 4.4	21.8	19.0 - 24.5		
Nova																														
Stat Profile 1-9	6.89	6.86 - 6.92	89	77 - 101	23	8 - 38	3.06	2.56 - 3.56	86	81 - 91	11.6	9.1 - 14.1	71	66 - 76			442	392 - 492	15.4	11.9 - 18.9	128.8	138.0 - 120.2	11.9	10.3 - 13.5	3.1	1.1 - 5.1	24.5	21.8 - 27.3		
Stat Profile 10	6.86	6.83 - 6.89	91	79 - 103	21	6 - 36			86	81 - 91	11.8	9.3 - 14.3	71	66 - 76			452	402 - 502	15.4	11.9 - 18.9	138.0	147.9 - 128.8	12.1	10.5 - 13.7	2.8	0.8 - 4.8	25.1	22.3 - 27.9		
Stat Profile Ultra A-M	6.90	6.87 - 6.93	86	74 - 98	21	6 - 36	3.06	2.56 - 3.56	86	81 - 91	11.8	9.3 - 14.3	71	66 - 76	DNA ²		452	402 - 502	15.4	11.9 - 18.9	125.9	134.9 - 117.5	11.5	9.9 - 13.1	2.8	0.8 - 4.8	25.1	22.3 - 27.9		
Nova 8							2.97	2.47 - 3.47	86	81 - 91	ORL ¹					2.15	1.75 - 2.55													
Radiometer																														
ABL 3, 30	6.85	6.82 - 6.88	89	77 - 101	30	15 - 45															141.3	151.4 - 131.8	11.9	10.3 - 13.5	4.0	2.0 - 6.0				
ABL 300, 330	6.85	6.82 - 6.88	89	77 - 101	29	14 - 44															141.3	151.4 - 131.8	11.9	10.3 - 13.5	3.9	1.9 - 5.9				
ABL 4	6.84	6.81 - 6.87	89	77 - 101	32	17 - 47					11.3	8.8 - 13.8									144.5	154.9 - 134.9	11.9	10.3 - 13.5	4.3	2.3 - 6.3				
ABL 5	6.84	6.81 - 6.87	91	79 - 103	21	6 - 36															144.5	154.9 - 134.9	12.1	10.5 - 13.7	2.8	0.8 - 4.8				
ABL 50, 500, 505, 510, 520	6.84	6.81 - 6.87	90	78 - 102	36	21 - 51	3.23	2.73 - 3.73	85	80 - 90	11.2	8.7 - 13.7	66	61 - 71							144.5	154.9 - 134.9	12.0	10.4 - 13.6	4.8	2.8 - 6.8				
ABL 600, 605, 610, 615, 620, 625	6.84	6.81 - 6.87	90	78 - 102	36	21 - 51	3.23	2.73 - 3.73	85	80 - 90	11.2	8.7 - 13.7	66	61 - 71			412	362 - 462	14.7	11.2 - 18.2	144.5	154.9 - 134.9	12.0	10.4 - 13.6	4.8	2.8 - 6.8	22.9	20.1 - 25.6		
ABL 700, 705, 710, 715, 720, 725	6.84	6.81 - 6.87	88	76 - 100	39	24 - 54	3.27	2.77 - 3.77	85	80 - 90	11.2	8.7 - 13.7	67	62 - 72			415	365 - 465	14.7	11.2 - 18.2	144.5	154.9 - 134.9	11.7	10.1 - 13.3	5.2	3.2 - 7.2	23.0	20.3 - 25.8		
EML 100, 105							3.23	2.73 - 3.73	85	80 - 90	11.2	8.7 - 13.7	66	61 - 71			412	362 - 462	14.7	11.2 - 18.2							22.9	20.1 - 25.6		
ICA, KNA 1							3.15	2.65 - 3.65	84	79 - 89	11.2	8.7 - 13.7																		
KNA 2									89	84 - 94	11.2	8.7 - 13.7																		
Roche																														
AVL 945, 947	6.83	6.80 - 6.86	90	78 - 102	35	20 - 50															147.9	158.5 - 138.0	12.0	10.4 - 13.6	4.7	2.7 - 6.7				
AVL 990, 995	6.83	6.80 - 6.86	89	77 - 101	36	21 - 51															147.9	158.5 - 138.0	11.9	10.3 - 13.5	4.8	2.8 - 6.8				
AVL Compact	6.83	6.80 - 6.86	90	78 - 102	36	21 - 51															147.9	158.5 - 138.0	12.0	10.4 - 13.6	4.8	2.8 - 6.8				
OMNI 1-9	6.88	6.85 - 6.91	90	78 - 102	21	6 - 36	3.06	2.56 - 3.56	86	81 - 91	11.4	8.9 - 13.9	74	69 - 79			420	370 - 470	16.0	12.5 - 19.5	131.8	141.3 - 123.0	12.0	10.4 - 13.6	2.8	0.8 - 4.8	23.3	20.5 - 26.1		
YSI																														
2300 Stat Plus																					432	382 - 482	16.2	12.7 - 19.7					24.0	21.2 - 26.8

Footnotes:

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