QC 823 Range Blood Gas • Electrolyte • Metabolite Control

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RNA® MEDICAL

QC 823 RANGE

Level 5

Blood Gas • Electrolyte • Metabolite Control

LOT 74211

Exp.: 2010-02

REF QC 823-5

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 CO_2, O_2, and N_2. 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_2 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.

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

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

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Level 5

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Expected Values Chart

	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	
Manufacturer / Analyzer	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	7.81	7.77 - 7.85	12	8 - 16	463	403 - 523															15.5	17.0 - 14.1	1.6	1.1 - 2.1	61.7	53.7 - 69.7		
248	7.81	7.77 - 7.85	12	8 - 16	463	403 - 523															15.5	17.0 - 14.1	1.6	1.1 - 2.1	61.7	53.7 - 69.7		
278, 280	7.81	7.77 - 7.85	12	8 - 16	478	418 - 538															15.5	17.0 - 14.1	1.6	1.1 - 2.1	63.7	55.7 - 71.7		
288	7.81	7.77 - 7.85	12	8 - 16	483	423 - 543	ORL [1]		166	161 - 171	1.2	0.7 - 1.7	133	128 - 138							15.5	17.0 - 14.1	1.6	1.1 - 2.1	64.4	56.4 - 72.4		
840, 845, 850, 855, 860, 865	7.83	7.79 - 7.87	12	8 - 16	443	383 - 503	0.22	0.12 - 0.32	166	161 - 171	1.4	0.9 - 1.9	130	125 - 135			ORL [1]		9.8	7.3 - 12.3	14.8	16.2 - 13.5	1.6	1.1 - 2.1	59.1	51.1 - 67.0	ORL [1]	
634	7.81	7.77 - 7.85					0.19	0.09 - 0.29																				
614, 644									167	162 - 172	1.6	1.1 - 2.1	134	129 - 139														
IL																												
1304, 1306, 1312	7.78	7.74 - 7.82	14	10 - 18	463	403 - 523															16.6	18.2 - 15.1	1.9	1.3 - 2.4	61.7	53.7 - 69.7		
BG3	7.79	7.75 - 7.83	12	8 - 16	473	413 - 533															16.2	17.8 - 14.8	1.6	1.1 - 2.1	63.1	55.1 - 71.0		
BGE	7.79	7.75 - 7.83	13	9 - 17	473	413 - 533	0.22	0.12 - 0.32	164	159 - 169	1.4	0.9 - 1.9									16.2	17.8 - 14.8	1.7	1.2 - 2.3	63.1	55.1 - 71.0		
1610, 1620, 1630, 1640, 1650	7.79	7.75 - 7.83	11	7 - 15	463	403 - 523	0.22	0.12 - 0.32	166	161 - 171	1.4	0.9 - 1.9	DNA [2]								16.2	17.8 - 14.8	1.5	0.9 - 2.0	61.7	53.7 - 69.7		
Synthesis 10, 15, 20, 25, 30, 35	7.81	7.77 - 7.85	13	9 - 17	468	408 - 528	0.19	0.09 - 0.29	165	160 - 170	1.8	1.3 - 2.3	130	125 - 135			0	0 - 5			15.5	17.0 - 14.1	1.7	1.2 - 2.3	62.4	54.4 - 70.4	0.0	0.0 - 0.3
Nova																												
Stat Profile 1-9	7.80	7.76 - 7.84	12	8 - 16	463	403 - 523	0.19	0.09 - 0.29	168	163 - 173	1.8	1.3 - 2.3	133	128 - 138			0	0 - 5	11.1	8.6 - 13.6	15.8	17.4 - 14.5	1.6	1.1 - 2.1	61.7	53.7 - 69.7	0.0	0.0 - 0.3
Stat Profile 10	7.80	7.76 - 7.84	12	8 - 16	473	413 - 533			168	163 - 173	1.6	1.1 - 2.1	133	128 - 138			0	0 - 5	11.1	8.6 - 13.6	15.8	17.4 - 14.5	1.6	1.1 - 2.1	63.1	55.1 - 71.0	0.0	0.0 - 0.3
Stat Profile Ultra A-M	7.82	7.78 - 7.86	12	8 - 16	465	405 - 525	0.19	0.09 - 0.29	169	164 - 174	1.6	1.1 - 2.1	133	128 - 138	DNA [2]		0	0 - 5	11.1	8.6 - 13.6	15.1	16.6 - 13.8	1.6	1.1 - 2.1	62.0	54.0 - 70.0	0.0	0.0 - 0.3
Nova 8							0.27	0.17 - 0.37	169	164 - 174	1.6	1.1 - 2.1			0.12	0.07 - 0.17												
Radiometer																												
ABL 3, 30	7.82	7.78 - 7.86	12	8 - 16	438	378 - 498															15.1	16.6 - 13.8	1.6	1.1 - 2.1	58.4	50.4 - 66.4		
ABL 300, 330	7.81	7.77 - 7.85	13	9 - 17	433	373 - 493															15.5	17.0 - 14.1	1.7	1.2 - 2.3	57.7	49.7 - 65.7		
ABL 4	7.80	7.76 - 7.84	13	9 - 17	428	368 - 488					1.5	1.0 - 2.0									15.8	17.4 - 14.5	1.7	1.2 - 2.3	57.1	49.1 - 65.1		
ABL 5	7.79	7.75 - 7.83	12	8 - 16	493	433 - 553															16.2	17.8 - 14.8	1.6	1.1 - 2.1	65.7	57.7 - 73.7		
ABL 50, 500, 505, 510, 520	7.80	7.76 - 7.84	12	8 - 16	448	388 - 508	0.21	0.11 - 0.31	165	160 - 170	1.5	1.0 - 2.0	128	123 - 133							15.8	17.4 - 14.5	1.6	1.1 - 2.1	59.7	51.7 - 67.7		
ABL 600, 605, 610, 615, 620, 625	7.80	7.76 - 7.84	12	8 - 16	448	388 - 508	0.21	0.11 - 0.31	165	160 - 170	1.6	1.1 - 2.1	128	123 - 133			0	0 - 5	10.4	7.9 - 12.9	15.8	17.4 - 14.5	1.6	1.1 - 2.1	59.7	51.7 - 67.7	0.0	0.0 - 0.3
ABL 700, 705, 710, 715, 720, 725	7.80	7.76 - 7.84	12	8 - 16	443	383 - 503	0.22	0.12 - 0.32	166	161 - 171	1.7	1.2 - 2.2	130	125 - 135			0	0 - 5	10.7	8.2 - 13.2	15.8	17.4 - 14.5	1.6	1.1 - 2.1	59.1	51.1 - 67.0	0.0	0.0 - 0.3
EML 100, 105							0.21	0.11 - 0.31	165	160 - 170	1.5	1.0 - 2.0	128	123 - 133			0	0 - 5	10.4	7.9 - 12.9							0.0	0.0 - 0.3
ICA, KNA 1							0.21	0.11 - 0.31	165	160 - 170	1.5	1.0 - 2.0																
KNA 2									167	162 - 172	1.6	1.1 - 2.1																
Roche																												
AVL 945, 947	7.78	7.74 - 7.82	12	8 - 16	463	403 - 523															16.6	18.2 - 15.1	1.6	1.1 - 2.1	61.7	53.7 - 69.7		
AVL 990, 995	7.78	7.74 - 7.82	13	9 - 17	477	417 - 537															16.6	18.2 - 15.1	1.7	1.2 - 2.3	63.6	55.6 - 71.6		
AVL Compact	7.80	7.76 - 7.84	12	8 - 16	472	412 - 532															15.8	17.4 - 14.5	1.6	1.1 - 2.1	62.9	54.9 - 70.9		
OMNI 1-9	7.77	7.73 - 7.81	13	9 - 17	433	373 - 493	0.16	0.06 - 0.26	170	165 - 175	1.6	1.1 - 2.1	134	129 - 139			ORL [1]		11.7	9.2 - 14.2	17.0	18.6 - 15.5	1.7	1.2 - 2.3	57.7	49.7 - 65.7	ORL [1]	
YSI																												
2300 Stat Plus																	0	0 - 5	11.9	9.4 - 14.4							0.0	0.0 - 0.3

Footnotes:

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

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