

Blood Gas • Electrolyte • Metabolite Control

LOT 74222

 2020-01

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.

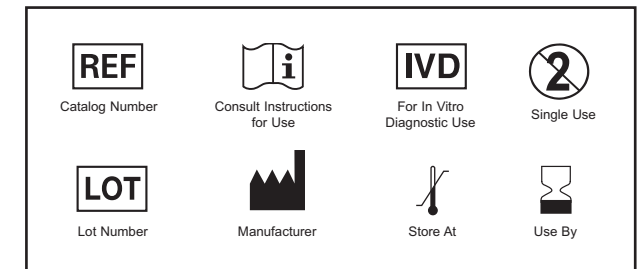
STATISTICAL SUPPORT

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

- 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 Bionosits, Inc.



INSTRUMENT MANUFACTURERS

Epocal Incorporated, Ottawa, ON, Canada
 Instrumentation Laboratory, Bedford, 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


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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		
Epocal																														
EPOC	7.85	7.79 - 7.91	14	10 - 18	490	400 - 580	0.22	0.12 - 0.32	171	165 - 177	DNA ²				0	0 - 10	DNA ²				1.9	1.3 - 2.4	65.3	53.3 - 77.3	0.0	0.0 - 0.6				
IL																														
GEM Premier 3000 Series	ORL ¹		13	9 - 17	465	405 - 525	0.13	0.03 - 0.23	177	172 - 182	1.4	0.9 - 1.9					DNA ²	DNA ²			ORL ¹	1.7	1.2 - 2.3	62.0	54.0 - 70.0	DNA ²				
GEM Premier 4000 Series	7.84	7.80 - 7.88	13	9 - 17	470	410 - 530	0.13	0.03 - 0.23	164	159 - 169	1.4	0.9 - 1.9	136	131 - 141			ORL ¹	11.3	8.8 - 13.8	14.5	15.8 - 13.2	1.7	1.2 - 2.3	62.7	54.7 - 70.6	ORL ¹				
GEM Premier 5000 Series	7.85	7.81 - 7.89	17	12 - 22	438	394 - 482	0.14	0.04 - 0.24	165	160 - 170	1.4	0.9 - 1.9	132	125 - 139			DNA ²	11.4	9.7 - 13.1	14.1	15.5 - 12.9	2.3	1.6 - 2.9	58.4	52.5 - 64.2	DNA ²				
Medica																														
EasyBloodGas	7.80	7.75 - 7.85	13	9 - 17	479	429 - 529															15.8	17.8 - 14.1	1.7	1.2 - 2.3	63.9	57.2 - 70.5				
EasyStat	7.82	7.77 - 7.87	14	10 - 18	477	427 - 527	0.25	0.15 - 0.35	172	167 - 177	1.4	0.9 - 1.9	128	123 - 133							15.2	17.0 - 13.5	1.9	1.3 - 2.4	63.6	56.9 - 70.2				
Nova																														
CCX, pHox Ultra	7.79	7.75 - 7.83	14	10 - 18	490	430 - 550	0.25	0.15 - 0.35	168	163 - 173	1.6	1.1 - 2.1	132	127 - 137	DNA ²		DNA ²	12.0	9.5 - 14.5	16.2	17.8 - 14.8	1.9	1.3 - 2.4	65.3	57.3 - 73.3	DNA ²				
pHox	7.81	7.77 - 7.85	14	10 - 18	510	450 - 570															15.5	17.0 - 14.1	1.9	1.3 - 2.4	68.0	60.0 - 76.0				
pHox Plus	7.79	7.75 - 7.83	14	10 - 18	520	460 - 580	DNA ²		167	162 - 172	1.6	1.1 - 2.1	126	121 - 131			DNA ²	DNA ²			16.2	17.8 - 14.8	1.9	1.3 - 2.4	69.3	61.3 - 77.3	DNA ²			
Prime	Call Nova Biomedical Hotline 1-800-545-6682 for assigned values																													
OPTI Medical																														
OPTI CCA	7.78	7.72 - 7.84	16	14 - 19	492	432 - 552	0.27	0.22 - 0.32	175	165 - 185	1.5	1.0 - 2.0	134	128 - 140			DNA ²	10.5	8.0 - 13.0	ORL ¹	2.1	1.9 - 2.5	65.6	57.6 - 73.6	ORL ¹					
OPTI R	DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²				DNA ²	DNA ²			ORL ¹	DNA ²		DNA ²						
OPTI LION	7.90	7.84 - 7.96					DNA ²		178	171 - 185	1.3	0.8 - 7.5	137	129 - 145							7.9	7.8 - 8.0								
Radiometer																														
ABL 700 Series	7.79	7.75 - 7.83	13	9 - 17	450	390 - 510	0.33	0.23 - 0.43	166	161 - 171	1.7	1.2 - 2.2	130	125 - 135			0	0 - 5	10.8	8.3 - 13.3	16.2	17.8 - 14.8	1.7	1.2 - 2.3	60.0	52.0 - 68.0	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	DNA ²		DNA ²		DNA ²				
ABL 800 Series	7.79	7.75 - 7.83	13	9 - 17	450	390 - 510	0.33	0.23 - 0.43	166	161 - 171	1.7	1.2 - 2.2	131	126 - 136			0	0 - 5	10.8	8.3 - 13.3	16.2	17.8 - 14.8	1.7	1.2 - 2.3	60.0	52.0 - 68.0	0.0	0.0 - 0.3		
ABL 90 Series	DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²		DNA ²				DNA ²	DNA ²			DNA ²	DNA ²		DNA ²		DNA ²				
Roche																														
Cobas b 221	7.76	7.72 - 7.80	13	9 - 17	490	430 - 550	DNA ²		DNA ²		DNA ²		DNA ²				DNA ²	DNA ²			17.4	19.1 - 15.8	1.7	1.2 - 2.3	65.3	57.3 - 73.3	DNA ²			
OMNI 1-9	7.74	7.70 - 7.78	14	10 - 18	445	385 - 505	0.21	0.11 - 0.31	170	165 - 175	1.6	1.1 - 2.1	133	128 - 138			ORL ¹	11.8	9.3 - 14.3	18.2	20.0 - 16.6	1.9	1.3 - 2.4	59.3	51.3 - 67.3	ORL ¹				
Siemens																														
238	7.80	7.76 - 7.84	13	9 - 17	480	420 - 540															15.8	17.4 - 14.5	1.7	1.2 - 2.3	64.0	56.0 - 72.0				
248	7.80	7.76 - 7.84	13	9 - 17	480	420 - 540															15.8	17.4 - 14.5	1.7	1.2 - 2.3	64.0	56.0 - 72.0				
400 Series	ORL ¹		ORL ¹		476	416 - 536	ORL ¹		170	160 - 180	1.5	1.0 - 2.0	132	122 - 142			ORL ¹				ORL ¹	ORL ¹	ORL ¹	63.5	55.5 - 71.4	ORL ¹				
800 Series	7.83	7.79 - 7.87	13	9 - 17	446	386 - 506	0.26	0.16 - 0.36	162	157 - 167	1.4	0.9 - 1.9	130	125 - 135			ORL ¹	9.9	7.4 - 12.4	14.8	16.2 - 13.5	1.7	1.2 - 2.3	59.5	51.5 - 67.4	ORL ¹				
500 Series	ORL ¹		ORL ¹		476	416 - 536	ORL ¹		170	160 - 180	1.5	1.0 - 2.0	131	121 - 141			ORL ¹	DNA ²			ORL ¹	ORL ¹	ORL ¹	63.5	55.5 - 71.4	ORL ¹				
1200 Series	7.83	7.79 - 7.87	12	8 - 16	490	430 - 550	ORL ¹		162	157 - 167	1.4	0.9 - 1.9	131	126 - 136			ORL ¹	11.4	8.9 - 13.9	14.8	16.2 - 13.5	1.6	1.1 - 2.1	65.3	57.3 - 73.3	ORL ¹				

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