

# QC 463

# EQUIL<sup>®</sup> PLUS WITH GLUCOSE AND LACTATE CONTROL

## INTENDED USE

RNA Medical<sup>®</sup> Brand QC 463 EQUIL Plus with Glucose and Lactate Control is a quality control material that, once tonometered, is used for monitoring the performance of blood gas, electrolyte, metabolite, and CO-Oximeter instrumentation. It may be used on most makes and models of multiple-test blood gas systems.

QC 463 provides a practical alternative to the use of human blood in tonometry. When tonometered with precise gas mixtures of oxygen and carbon dioxide using the RNA Medical EQUILibrator<sup>®</sup> Tonometer, it produces  $pO_2$  and  $pCO_2$  values that duplicate those of tonometered whole blood.

## PRODUCT DESCRIPTION

QC 463 is a bovine hemoglobin solution containing electrolytes, glucose, and lactate. This product contains no preservatives and no human-based materials. It is considered good laboratory practice to follow the recommended "Universal Precautions" when handling any blood product.

QC 463 is available in three (3) levels for monitoring pH,  $pCO_2$ ,  $pO_2$ ,  $Na^+$ ,  $K^+$ ,  $Cl^-$ ,  $Ca^{++}$ ,  $Mg^{++}$ , glucose, lactate, total hemoglobin, and hemoglobin fractions at varying points within the clinical range. Prior to use, QC 463 is tonometered with precision gas mixtures of  $CO_2$ ,  $O_2$ , and  $N_2$  to produce distinct control levels for pH,  $pCO_2$ ,  $pO_2$ , and  $O_2Hb$ . Additional tonometry gas mixtures may be used for low or elevated  $pO_2$  monitoring.

QC 463 is provided in convenient, ready-to-use ampuls containing 2.4 mL of solution. Ampuls are packaged in single level boxes (30 ampuls of the same level) or multi-level boxes (10 ampuls of each level).

## PERFORMANCE FEATURES

Although considered the reference procedure to establish the accuracy of blood  $pCO_2$  and  $pO_2$ ,<sup>1</sup> whole blood tonometry has been a cumbersome process in the past. QC 463 and the EQUILibrator Tonometer are easy to use and technique independent, greatly simplifying the process of tonometry.

The bovine hemoglobin in QC 463 has oxygen saturation properties, including a  $P_{50}$  and temperature coefficient, virtually identical to human blood. Aqueous, fluorocarbon, and blood-based "artificial" controls lack these oxygen saturation properties and cannot evaluate the accuracy of  $pO_2$  and  $pCO_2$ . Additionally, since it contains no human-based materials, laboratories using QC 463 can easily assess analyzer  $pO_2$  and  $pCO_2$  accuracy without the biohazards associated with the tonometry of human blood.

Once tonometered, QC 463 remains stable for up to one (1) hour in a capped syringe. There is sufficient volume to allow for repeat testing and use on multiple analyzers in several different lab locations.

Key features of QC 463 Controls are summarized below:

- Use of a procedure considered to be the "gold standard" for monitoring blood gas analyzer accuracy.
- A post-tonometry stability of up to one (1) hour in a capped syringe, making repeat testing and multiple analyzer use possible at no additional cost.
- The ability to monitor analyzer accuracy at critical  $pO_2$  levels (35-40 mmHg).
- Performance characteristics identical to human blood but without the biohazards associated with human-based materials.
- The benefits of tonometry with the convenience of an ampuled control, including multiple test parameters.

## STORAGE AND SHELF LIFE

QC 463 has a shelf life of twenty-one (21) months from the date of manufacture when stored at 2-8 °C. It may remain at room temperature (up to 25 °C) for seven (7) days, not exceeding the stated expiration date. This product should be protected from freezing and exposure to temperatures greater than 8 °C.

## STATISTICAL SUPPORT

The RNA Medical statistical service program is the new standard in inter-laboratory peer analysis. Only RNA offers true on-line data submission and reporting options in *real-time*. Monthly reports with cumulative and lot-specific peer comparison data can now be a valuable troubleshooting tool.

Specific features of the RNA program include:

- Optional on-line submission of either summary or raw data via the RNA Medical website.
- *Real-time* availability of monthly and peer comparison reports for internet submitted data, providing immediate access to statistical information.
- Error checking of data before submission to peer group, ensuring the integrity peer comparison data.
- Customized peer group options and reports.
- Acceptance of data not previously submitted (late data).
- Reprinting and replacement of lost reports with data current to the date of submission.

1. NCCLS. Blood Gas and pH Analysis and Related Measurements; Approved Guideline. NCCLS Document C46-A [ISBN 1-56238-444-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2001.

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## CONTROL VALUES AND ANALYTES

The  $p\text{CO}_2$  and  $p\text{O}_2$  values for tonometered QC 463 are calculated as follows:

$$p\text{O}_2 \text{ (or } p\text{CO}_2) \text{ in mmHg} = [\text{ambient barometric pressure} - 47^*] \times \% \text{O}_2 \text{ (or } \% \text{CO}_2) \text{ in the gas mixture}$$

(\*47 mmHg is the partial pressure of water vapor at 37 °C)

Values for all other parameters are provided with each box of controls. Refer to the QC 463 package insert for lot specific values for each listed analyzer.

The typical values for QC 463 when tonometered at a barometric pressure of 760 mmHg are as follows:

QC 463 Level	1	2	3	2a <sup>Δ</sup>	2b <sup>Δ</sup>
Gas Level	1	2	3	4	5
CO <sub>2</sub> (%)	9.8	5.6	2.8	5.6	5.6
O <sub>2</sub> (%)	14.0	9.8	5.6	21.0	42.0

### Analyte

pH	7.20	7.40	7.60	7.40	7.40
$p\text{CO}_2$ (mmHg)	70	40	20	40	40
$p\text{O}_2$ (mmHg)	100	70	40	150	299
Na <sup>+</sup> (mmol/L)	153	136	116	136	136
K <sup>+</sup> (mmol/L)	7.0	5.0	3.0	5.0	5.0
Cl <sup>-</sup> (mmol/L)	115	98	78	98	98
Ca <sup>++</sup> (mmol/L)	1.50	1.10	0.70	1.10	1.10
Mg <sup>++</sup> (mmol/L)	1.20	0.60	0.30	0.60	0.60
Glucose (mg/dL)	250	100	40	100	100
Lactate (mmol/L)	0.6	1.3	3.2	1.3	1.3
tHb (g/dL)	17.6	13.8	8.8	13.8	13.8
O <sub>2</sub> Hb (%)	95	93	87	93	93
COHb (%)	1.5	1.5	1.5	1.5	1.5
MetHb (%)	1.5	1.5	1.5	1.5	1.5
HHb (%)	2.0	2.0	8.0	2.0	2.0

Typical **untometered** blood gas values for QC 463 are:

pH	7.14	7.20	7.21
$p\text{CO}_2$ (mmHg)	93	93	93
$p\text{O}_2$ (mmHg)	2	2	2

Δ Level 2 QC 463 tonometered with elevated O<sub>2</sub> gas mixtures.

## QC 463 SPECIFICATIONS

Packaging: 2.4 mL per ampul, 30 ampuls per box.  
 Storage: 2-8 °C (up to 7 days at room temperature).  
 Shelf Life: 21 months from date of manufacture.  
 Matrix: Bovine hemoglobin solution.  
 Analytes: pH,  $p\text{CO}_2$ ,  $p\text{O}_2$ , Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, glucose, lactate, total hemoglobin, and hemoglobin fractions.

## ORDERING INFORMATION

RNA Medical can reserve a single lot of control for up to twelve (12) months. Pending availability and shelf life, additional sequestration may be possible. Automatic shipments may be arranged from a standing order on a predetermined frequency.

Please specify these catalog numbers when ordering RNA Medical QC 463 Controls.

*Catalog number* **QC 463-1** (Level 1)  
**QC 463-2** (Level 2)  
**QC 463-3** (Level 3)  
**QC 463** (Multi-level)

## ADDITIONAL PRODUCTS

RNA Medical has a broad line of blood gas and critical blood analyte control products, including Calibration Verification Controls with on-line graphing options. For further information about QC 463, Calibration Verification Controls, or any other RNA Medical product, please contact us at the number listed on the bottom of the page or visit our website at [www.RNAMedical.com](http://www.RNAMedical.com).

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