

Hematocrit Control

LOT

Low: 63907

High: 64007

Multi-Level: 63977



Exp.: Low: 2011-02

High: 2011-02

Multi-Level: 2011-02

REF

QC 900

IVDFor *In Vitro*
Diagnostic Use

INTENDED USE

RNA Medical® Brand QC 900 Hematocrit Control is an assayed quality control material used for monitoring the performance of analyzers measuring hematocrit by electrical conductivity that are listed on the Expected Values Chart.

PRODUCT DESCRIPTION

QC 900 is provided in two (2) levels (Low and High) for monitoring analyzer performance at different points within the clinical range. It is packaged in sealed glass ampuls, each containing 1.7 mL of solution. Ampuls are packaged twenty (20) per box (10 of each level).

Active Ingredients:

This product is an aqueous solution containing electrolytes and non-conductive ingredients. This control contains no red cells and no human or biological materials.

STORAGE

The expiration date stated on the packaging is for product stored at temperatures of 2-25 °C. Avoid freezing and temperatures greater than 30 °C.

DIRECTIONS FOR USE

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 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.

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 900 is sensitive to many instrument related factors that would affect analytical results. Because it does not contain red cells and 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.
3. QC 900 is intended for use on analyzers that measure hematocrit by electrical conductivity. It is not suitable for use on analyzers that do not utilize electrical conductivity methodology for hematocrit determination.


QC 900 Hematocrit Control

Expected Values Chart

Low

LOT 63907
 Exp.: 2011-02

High

LOT 64007
 Exp.: 2011-02

Hematocrit
%

Hematocrit
%

Manufacturer/Analyzer

mean

range

mean

range

IL

BGE, 1630, 1640, 1650	35	33 - 37	53	51 - 55
Synthesis	35	33 - 37	54	52 - 56

ITC

IRMA¹

Nova

Stat Profile 1-10, Ultra	34	32 - 36	51	49 - 53
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Radiometer

ABL 70	34	32 - 36	57	55 - 59
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Roche





OMNI 1-9	30	28 - 32	48	46 - 50
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Footnotes:

- Contact ITC Technical Support or the ITC website (www.itcmed.com) for assigned values.

INSTRUMENT MANUFACTURERS

Instrumentation Laboratory, Lexington, MA
 International Technidyne Corporation, Edison, NJ
 Nova Biomedical, Waltham, MA
 Radiometer America, Westlake, OH
 Roche Diagnostics, Indianapolis, IN

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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