

Hematocrit Control

REF QC 900

IVD

INTENDED USE

RNA Medical® Brand QC 900 Hematocrit Control is an unassayed quality control material used for monitoring the performance of analyzers measuring hematocrit by electrical conductivity.

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 a buffered 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

If stored refrigerated, the control material should be equilibrated to room temperature for at least four (4) hours prior to testing. Before use, gently invert the ampul 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

Lot specific assigned values are available from the instrument manufacturer. For the IRMA TRUpoint®, call ITC Technical Support or visit the ITC website (www.itcmed.com). For the EPOC™, call Epocal Technical Support or visit the Epocal website (www.epocal.com).

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 may turn slightly yellow in color over its shelf life if stored at room temperature. This coloration is normal and does not affect product performance.
3. 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.
4. 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.

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.

RNA Medical is a registered trademark and PeerQC is a registered service mark of Bionostics, Inc., Devens, MA USA. The products described herein are covered by U.S. Patent 7,027,931. IRMA TRUpoint is a registered trademark of International Technidyne Corporation, Edison, NJ USA. EPOC is a trademark of Epocal Inc, Ottawa, ON, Canada.

INSTRUMENT MANUFACTURERS

Epocal Inc., Ottawa, ON, Canada

International Technidyne Corporation, Edison, NJ

RNA Medical, Division of Bionostics, Inc.

7 Jackson Road
Devens, MA 01434 USA
978-772-9070 • 800-533-6162
www.RNAMEDICAL.com



Catalog Number



Consult Instructions for Use



For In Vitro Diagnostic Use



Lot Number



Manufacturer



Store At



Use By