Hematocrit Calibration Verification Controls

5 Levels

REF CVC 9005 IVD

INTENDED USE

RNA Medical® Brand *Hematocrit Calibration Verification Controls,* **Catalog Number CVC 9005**, are materials used for verifying the calibration and linearity of instruments that measure hematocrit by electrical conductivity, such as the IRMA TRUpoint® and the Epocal EPOC.™

PRODUCT DESCRIPTION

Hematocrit Calibration Verification Controls are provided in five (5) distinct levels for verifying hematocrit measurements throughout the reportable range. This product is packaged in sealed glass ampuls, each containing 1.7 mL of solution. Ampuls are packaged in kits containing four (4) ampuls of each level.

Active Ingredients:
This product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. It 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 exposure to freezing and temperatures greater than 30 °C.

EXPECTED VALUES

Contact the appropriate instrument manufacturer for lot specific assigned values. Call ITC Technical Support or visit www.itcmed.com or call Epocal Technical Support or visit www.epocal.com.

DIRECTIONS FOR USE

If stored refrigerated, the calibration verification material should be equilibrated to room temperature for at least four (4) hours prior to testing.

Refer to the instrument manufacturer's User Manual for use of the instrument and consumables and for test mode recommendations.

1. Beginning with Level 1, gently invert the ampul to mix the solution. Tap the ampul to restore the liquid to the bottom of the ampul.
2. Open the ampul by snapping off the tip at the score. Use gauze, tissue, gloves, or an appropriate ampul opener (Snapper ampul openers are included) to protect fingers from cuts.
3. Introduce the liquid from the ampul to the system according to manufacturer's instruction.
   Note: *Run calibration verification materials in the test mode recommended by the instrument manufacturer.*
4. Appropriately discard the ampul after use.
5. Record the results on the Data Collection and Linearity Worksheet.
   Note: *The only assigned value for this control is hematocrit. All other analyte results obtained with this material should be ignored.*
6. Repeat steps 1 through 5 for the remaining ampuls of Level 1 until three (3) replicates are completed (a fourth ampul of each level is provided in case of accidental breakage or obvious sampling error). Test Levels 2, 3, 4, and 5 the same way. Record all values on the worksheets.
7. Calculate the mean value and compare the mean to the range on the instrument manufacturer's value assignment sheet. If your mean is within the range, circle **Yes** on the Data Collection and Linearity Worksheet after the question **OK?**. If your mean is outside the range, circle **No** and take corrective action.
8. To graph the linearity of your results:
   a. Using the graph area provided, plot the test mean against the assigned mean.
   b. Connect the plotted points to visualize linearity.

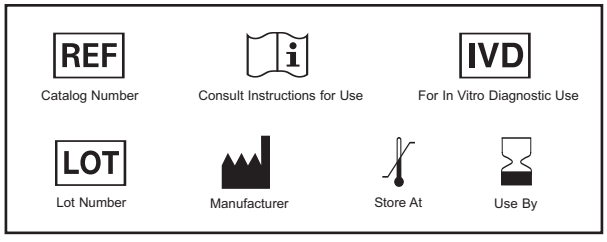
   Note: *Steps 7 and 8 may be performed on-line as a feature of PeerQC® described below.*

STATISTICAL SUPPORT

RNA Medical PeerQC®, available at www.RNAMedical.com, features web-based graphing and reporting for its Calibration Verification Controls. The graphing steps outlined above may be performed on-line as a feature of this service. Please contact RNA Medical or visit our website for information about utilizing PeerQC® for this product.

LIMITATIONS

1. RNA Medical Hematocrit Calibration Verification Controls are sensitive to many instrument related factors that would affect analytical results. Because it is not a blood-based material and does not contain red cells, 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 not for use as a calibration standard, and its use should not replace other aspects of a complete quality control program.
4. RNA Medical Hematocrit Calibration Verification Controls are intended for use on instruments that measure hematocrit. They are not suitable for use on instruments that do not utilize an electrical conductivity method for hematocrit determination.



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HEMATOCRIT CALIBRATION VERIFICATION CONTROLS

Data Collection and Linearity Worksheet

Date: _____ Analyzer Serial Number: _____

Analyzer: _____ Cartridge Lot Number: _____

	Level 1	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Lot #	_____	_____	_____	_____	_____
Test 1	_____	_____	_____	_____	_____
Test 2	_____	_____	_____	_____	_____
Test 3	_____	_____	_____	_____	_____
Test Mean	_____	_____	_____	_____	_____
Assigned Range	_____	_____	_____	_____	_____
OK?	**Yes or No**	**Yes or No**	**Yes or No**	**Yes or No**	**Yes or No**