

RNA_{1C}**Normal and Abnormal****Control for Siemens® DCA 2000® and DCA 2000+ Analyzers**

LOT Normal: 99604
Abnormal: 99704
Set: 99644

Exp.: Normal: 2010-09
Abnormal: 2010-09
Set: 2010-09

IVD**REF** QC A1C**INTENDED USE**

RNA Medical® Brand **RNA_{1C}** Control is an assayed quality control material used for monitoring the performance of Siemens DCA 2000 and DCA 2000+ Analyzers that measure HbA_{1C}.

PRODUCT DESCRIPTION

RNA_{1C} is provided in two (2) levels (normal and abnormal) for monitoring analyzer performance at significant points within the clinical range. RNA_{1C} is packaged in bottles, each containing 1.0 mL of solution. Each box contains two (2) bottles of normal control and two (2) bottles of abnormal control.

Active Ingredients:

RNA_{1C} is a dye-based aqueous solution containing buffers and stabilizers. This control contains no hemoglobin and no human or biological materials.

STORAGE

The expiration date stated on the RNA_{1C} packaging is for product stored refrigerated (2-8 °C). After opening, each bottle of control is stable for ninety (90) days if stored refrigerated or thirty (30) days if stored at room temperature (up to 25 °C). Bottles should be tightly closed after each use. Avoid exposing unopened bottles to freezing and temperatures greater than 8 °C.

Note: The revised expiration date for each opened bottle should be recorded on the bottle label.

DIRECTIONS FOR USE

Controls are analyzed in the same manner as patient samples. Refer to the DCA 2000 operator's manual and DCA 2000 Hemoglobin A_{1C} Reagent Kit package insert for complete instructions on how to analyze a sample.

Perform the following steps to fill the capillary with RNA_{1C} control:

1. Invert the control solution several times to ensure thorough mixing before use.
2. Twist open the cap, tilt the bottle at a downward angle, and gently squeeze the bottle so that a drop forms on the bottle tip.
3. Holding the capillary holder at an angle, touch the tip of the capillary to the formed drop until the capillary fills.

Note: If the control material comes in contact with the plastic capillary holder when the capillary is filled, discard the capillary holder and recollect the sample. Erroneous test results or error messages may occur.

4. Using a lint-free tissue, carefully wipe the outside of the capillary. Do not allow the tissue to touch the open end of the capillary. Sample loss may occur if the sample wicks into the tissue.
5. Analyze per the instructions in the DCA 2000 operator's manual and DCA 2000 Hemoglobin A_{1C} Reagent Kit package insert.

After each use, wipe the tip of the bottle, replace the cap, and immediately tighten. Do not use control solutions after the expiration date printed on the bottles and box, or after the open-bottle expiration date recorded on each bottle.

EXPECTED VALUES

The control values assigned to RNA_{1C} are based on multiple determinations performed on randomly selected samples from each lot. The listing 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 published expected value range.

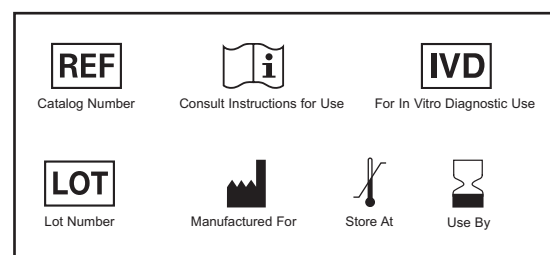
RNA Medical provides monthly statistical reports for tracking and review of analyzer performance as well as lot number specific peer group data. Please contact RNA Medical for information about this service.

LIMITATIONS

1. RNA_{1C} 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.
2. This product is intended for use as a quality control material and can assist in evaluating the performance of Siemens DCA 2000 and DCA 2000+ Analyzers. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

EXPECTED VALUES

	Normal		Abnormal	
	LOT	Exp.:	LOT	Exp.:
	99604	2010-09	99704	2010-09
HbA _{1C}	%		%	
	mean	range	mean	range
Siemens				
DCA 2000 and DCA 2000+	5.7	4.6 - 6.8	10.9	8.7 - 13.1



RNA Medical, Division of Bionostics, Inc.
7 Jackson Road
Devens, MA 01434, USA
978-772-9070 • 800-533-6162
www.RNAMedical.com

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