QC HGB

Low, Normal, High

Hemoglobin Control for HemoCue® Analyzers

LOT				REF		IVD
Low:	67231	Low:	2028-08-31	Low:	QC HGB-1	
Normal:	67332	Normal:	2028-08-31	Normal:	QC HGB-2	
High:	67430	High:	2028-08-31	High:	QC HGB-3	
Multi-Level:	672120	Multi-Level:	2028-08-31	Multi-Level:	QC HGB	

INTENDED USE
RNA Medical® Brand QC HGB Hemoglobin Control is an assayed quality control material used for monitoring the performance of HemoCue analyzers that are listed on the Expected Values Chart.

PRODUCT DESCRIPTION
QC HGB is provided in three (3) levels for monitoring analyzer performance at significant points within the clinical range. It is packaged in bottles, each containing 3.0 mL of control solution. Bottles are packaged six (6) per box.

Active Ingredients:
QC HGB contains a solution of unfixed stabilized human erythrocytes and preservatives.

Precautions:
This product contains human source materials that have tested non-reactive for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), hepatitis C virus (HCV), anti-HIV-1, anti-HIV-2, and human T-cell lymphotrophic virus type 1 (HTLV-1). Since no known test method can offer complete assurance that specimens of human origin will not transmit infectious disease, this control should be handled as a potentially biohazardous material. Follow the recommended "Universal Precautions" when handling this and any blood product.

Disposal of this product should be according to the practices of your institution for infectious medical waste. Discard all materials in a safe and acceptable manner and in compliance with all federal, state and local requirements.

STORAGE
The expiration date stated on the packaging is for product stored refrigerated (2-8 °C). After opening, each bottle of control is stable for sixty (60) 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 temperatures greater than 8 °C. Do not freeze.

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

DIRECTIONS FOR USE
Refer to the HemoCue operator's manual for complete instructions on how to analyze a control material. To prepare the control sample, follow the steps below:

1. If refrigerated, place the bottle(s) of control solution to be analyzed at room temperature (15-25 °C) for 20 minutes prior to use.
2. Thoroughly mix by gently inverting the bottle and rolling between the palms until all cellular components are completely suspended. Do not shake or use a mechanical mixer.
3. Twist open the cap, tilt the bottle at a downward angle, and gently squeeze the bottle so that a drop forms.
4. Immediately introduce the control material to the analyzer, following the manufacturer's instructions.

   Note: *A drop of control may be dispensed onto a clean, disposable, non-absorbent material to assist with sampling.*

5. After each use, wipe the tip and threads of the bottle and cap. Replace the cap and immediately tighten.

Return the opened bottle(s) to the chosen open-bottle storage temperature immediately after use. 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 QC HGB 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.

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.

LIMITATIONS
1. QC HGB is sensitive to many instrument related factors that would affect analytical results. Although it contains human red cells, it does not contain the other components of a whole blood sample. Therefore, it may not detect certain malfunctions that would affect the testing of whole blood.
2. This product is intended for use as a quality control material and can assist in evaluating the performance of hemoglobin analyzers. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.
3. Exposure to freezing or temperatures greater than 25 °C may affect product performance. If the cellular components appear to be grossly hemolyzed or visually clumped after proper mixing, the control is unsuitable for use and should be discarded.
4. Erroneous test results may occur if the controls are not mixed thoroughly. Follow mixing instructions carefully prior to use.

HemoCue is a registered trademark of HemoCue AB Corporation, Angelholm, Sweden. RNA Medical is a registered trademark of Bionostics, Inc., Devens, MA, USA. PeerQC is a registered service mark of Bionostics, Inc., Devens, MA, USA, covered by U.S. Patent 7,027,931.

EXPECTED VALUES

Low

LOT 67231
2028-08-31

Hemoglobin g/dL

Manufacturer/Analyzer	*mean*	*range*
HemoCue		
Hb 201+	6.1	5.4 - 6.8

Normal

LOT 67332
2028-08-31

Hemoglobin g/dL

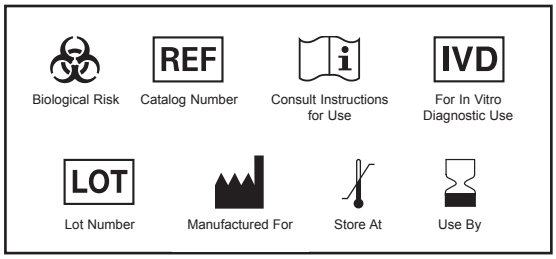
Manufacturer/Analyzer	*mean*	*range*
HemoCue		
Hb 201+	13.3	12.3 - 14.3

High

LOT 67430
2028-08-31

Hemoglobin g/dL

Manufacturer/Analyzer	*mean*	*range*
HemoCue		
Hb 201+	17.6	16.2 - 19.0



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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