

HEMA-Trol™ Whole Blood HGB

Whole Blood Hemoglobin Control

For HemoCue® B-Hemoglobin Photometers

NERL Diagnostics, East Providence, RI 02914

For use as a reference control for HemoCue analyzers in the measurement of hemoglobin.

For In Vitro Diagnostic Use.

Store at 2° to 8°C.

Caution: Contains human source material. Handle as potentially infectious. See insert for details.

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For In Vitro Diagnostic Use.

INTENDED USE

HEMA-Trol™ Whole Blood HGB Control is a multi-level reference control designed for use on HemoCue B-Hemoglobin photometers.

SUMMARY AND PRINCIPLE

Accepted laboratory procedure requires that stable reference controls be periodically used to monitor accuracy and precision. HEMA-Trol HGB Control may be used as one would use whole blood in obtaining the stated parameters for HemoCue photometers.

REAGENTS

HEMA-Trol HGB Control is composed of unfixed, stabilized human erythrocytes suspended in a bacteriostatic and fungistatic solution.

WARNINGS AND PRECAUTIONS

Warning: Potentially Biohazardous Material

Each donor unit used in the preparation of HEMA-Trol HGB Control has been tested and found to be non-reactive for hepatitis B surface antigen (HB_sAg), hepatitis B core (HB_c) antibody, hepatitis C virus, and anti-HIV-1, as well as for anti-HIV-2 and the human T-cell lymphotropic virus type 1 (HTLV-1).

Because no test method can offer complete assurance that HIV, HB_sAg, or other infectious agents are absent, it is recommended that HEMA-Trol HGB Control be handled with the same precautions used for patient specimens.

HEMA-Trol HGB Control should be treated the same as a patient specimen and run in accordance with the instructions accompanying the instrument being used.

HEMA-Trol HGB Control is intended solely for in vitro diagnostic use for the purpose described on the labeling. NERL Diagnostics shall not be liable for any claimed damages arising from any other usage.

STORAGE AND STABILITY

HEMA-Trol HGB Control is stable through the expiration date indicated on the labeling, when stored at 2-8°C. After opening, vials may be used for up to 60 days stored at 2-8°C or 30 days stored at room temperature.

PROCEDURE

1. Allow the vials to come to room temperature (15° - 30°C) for 20 minutes.

2. Mix thoroughly by gently inverting the vials and rolling them between the palms until all cellular components are completely suspended. A mechanical mixer is not recommended for this procedure but can be used to *maintain* the cell suspension. Do not shake the vial.
3. Remove the cap from the vial. Dispense a drop of product onto parafilm or another clean, non-absorbent material. Fill the HemoCue microcuvette with HEMA-Trol HGB Control as you would a patient sample.
4. Follow the instrument manufacturer's instructions. Values should be read within two minutes of loading the sample.
5. Wipe the tip and threads of the vial clean prior to recapping. Recap the vials immediately and return them to the refrigerator.

EXPECTED RESULTS

An expected range is given for each level based on data generated from multiple lab analyses using HemoCue photometers. Variations between labs will be greater than the precision for any one instrument. Results depend upon differences in equipment, reagents, supplies and techniques. Therefore, a laboratory should establish its own acceptable ranges. If the controls fail to perform consistently within expected ranges, contact NERL Diagnostics at (800) 556-7575.

INDICATION OF DETERIORATION

If, after following the specific mixing procedures, the cellular components of HEMA-Trol HGB Control appear to be grossly hemolyzed or appear to be visually clumped or aggregated, do not use. Call NERL Diagnostics Technical Services at (800) 556-7575.

SPECIFIC PERFORMANCE CHARACTERISTICS

HEMA-Trol HGB Control is a reliable liquid product manufactured under rigid quality control standards. To obtain good results, the product requires proper storage and handling as described.

LIMITATIONS OF THE PROCEDURE

1. HEMA-Trol HGB Control may not be appropriate for certain instruments other than the HemoCue photometer. Call NERL Diagnostics Technical Services at (800) 556-7575 for information.
2. Inaccuracies in test results may occur as a result of inappropriate mixing procedures. Precisely follow all mixing instructions before sampling.

BIBLIOGRAPHY

HemoCue B-Hemoglobin Photometer Operating Manual, HemoCue AB, Angelholm, Sweden.

HemoCue B-Hemoglobin Microcuvette Package Insert, HemoCue AB, Angelholm, Sweden.

Koepke, Bull, Giimer and Goldblatt: Hematology in Quality Assurance Practices for Health Laboratories. Interdisciplinary Books: American Public Health Assn., 1978.

Banauch et al. Z. Klin. Chem. u. Klin. Biochem, 13, 101-107 (1975).

Bergmeyer: Methods of Enzymatic Analysis 1 (1974), Chemie publishers, Weinheim.

ORDERING INFORMATION

Product Number	Description	Volume	Packaging
HYC84665	HEMA-Trol HGB Control (1 x 3ml each level)	9 ml	3 x 3ml
HYC84666	HEMA-Trol HGB Control (Low)	18 ml	6 x 3ml
HYC84667	HEMA-Trol HGB Control (Normal)	18 ml	6 x 3ml
HYC84668	HEMA-Trol HGB Control (High)	18 ml	6 x 3ml
HYC84669	HEMA-Trol HGB Control (2 x 3ml each level)	18 ml	6 x 3ml

Standing orders may be scheduled through NERL Diagnostics. Please direct all ordering inquiries to Customer Service at the address listed below.

HEMA-Trol is a trademark of NERL Diagnostics, East Providence, RI 02914.

HemoCue is a registered trademark of HemoCue Inc., Mission Viejo, CA.



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