

Cat. No. 503000**Hemoglobin Controls***For In Vitro Diagnostic Use.*

A bi-level reference control intended for use on STAT-Site[®] and HemoSite[®] hemoglobin testing systems, including the STAT-Site[®] M¹⁰⁰ Test System.

Summary and Principle

Controls, when assayed as actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision. STAT-Site[®] Hemoglobin Control, Cat No. 503000, may be used as one would use whole blood in obtaining the stated parameters for the STAT-Site[®] and HemoSite[®] hemoglobin testing systems.

Reagents**Hemoglobin Control, Cat. No. 503010 - Low Level (1.5mL/vial)**

Prepared from unfixed, stabilized human erythrocytes suspended in a bacteriostatic and fungistatic solution, containing a low-normal level of hemoglobin.

Hemoglobin Control, Cat. No. 503020 - High Level (1.5mL/vial)

Prepared from unfixed, stabilized human erythrocytes suspended in a bacteriostatic and fungistatic solution, containing a high-normal level of hemoglobin.

Warning and Precautions

For In Vitro Diagnostic Use.

Each donor unit used in the preparation of STAT-Site[®] Hemoglobin 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, HBsAg, or other infectious agents are absent, it is recommended that STAT-Site[®] Hemoglobin Control be handled with the same precautions used for patient specimens.

STAT-Site[®] Hemoglobin Control should be treated the same as a patient specimen and run in accordance with the instructions accompanying the instrument being used.

STAT-Site[®] Hemoglobin Control is intended solely for *in vitro* diagnostic use for the purpose described on the labeling. The manufacturer shall not be liable for any claimed damages arising from any other usage.

Indication of Deterioration

If, after following the specific mixing procedures, the cellular components of STAT-Site[®] Hemoglobin Control appear to be grossly hemolyzed or appear to be visually clumped or aggregated, do not use. Contact Stanbio Technical Service at (800) 531-5535.

Storage and Stability

Control is stable until expiration date, when stored unopened at 35° - 46°F (2-8°C). After opening, control may be used for up to 60 days stored at 35° - 46°F (2-8°C), or 30 days stored at room temperature, 59° - 86°F (15°-30°C).

Specific Performance Characteristics

STAT-Site[®] Hemoglobin 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.

Preparation

1. Allow the vials to come to room temperature 59° - 86°F (15°-30°C) for 20 minutes.
2. Mix thoroughly but gently by inverting the vials and repeatedly rolling them between the palms until all cellular components are completely suspended. Check the bottom of the vial to make sure that all cells are completely suspended and not settled in the bottom of the vial. A mechanical mixer is not recommended for the procedure but can be used to maintain the cell suspension. **Do not shake the vial.**
3. Remove the cap from the vial. Completely invert the vial and then gently squeeze the vial to form a drop on the tip. Take care to avoid spilling.
4. Following the instrument manufacture's instructions for testing, gently touch the drop to the center of the Test Card.
5. While waiting for results, clean the threads of the vial and threads of the cap with a cotton or polyester gauze. Snugly recap the vials immediately. After testing, return the vial to the refrigerator if desired.

Limitations of the Procedure

1. STAT-Site[®] Hemoglobin Control may not be appropriate for certain instruments other than the GDS[®] Hemoglobin Test Systems (STAT-Site[®], STAT-Site[®] M, and HemoSite[®]).
2. Inaccuracies in test results may occur as a result of inappropriate mixing procedures. Precisely follow all mixing instructions before testing.

Results

An expected range is given for each level based on data generated from multiple lab analyses using STAT-Site[®] and HemoSite[®] meters. 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 Stanbio Technical Service at (800) 531-5535.

Expected Range

<u>Control</u>	<u>Lot No.</u>	<u>Exp.</u>	<u>Range</u>
Low Level	06381	03/09	9.3 - 13.1 g/dL
High Level	06382	03/09	13.2 - 17.4 g/dL

Ordering Information

Catalog Number 503000 • STAT-Site[®] Hemoglobin Controls
6 x 1.5ml (2 each Low and High Levels)

CLIAwaived.com[™]

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