

# HemoPoint® H2 Hemoglobin Controls

Cat. No. 3060

For In Vitro Diagnostic Use.

A tri-level reference control set intended for use on **HemoPoint® H2 Hemoglobin testing system.**

## Summary and Principle For Information Use Only

Controls, when assayed as actual specimens, help a laboratory evaluate whether a given procedure is performing with acceptable accuracy and precision. **HemoPoint® H2 Hemoglobin Controls**, Cat No. 3060, may be used as one would use whole blood in obtaining the stated parameters for the **HemoPoint® H2 hemolobin testing system.**

## Reagents

### Hemoglobin Control, Cat. No. 3061 Low Level (1.5mL/vial)

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

### Hemoglobin Control, Cat. No. 3062 Normal Level (1.5mL/vial)

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

### Hemoglobin Control, Cat. No. 3063 High Level (1.5mL/vial)

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

## Warning and Precautions

For In Vitro Diagnostic Use.

Each donor unit used in the preparation of **HemoPoint® H2 Hemoglobin Controls** has been tested and found to be non-reactive for hepatitis B surface antigen (HB<sub>s</sub>Ag), hepatitis B core (HB<sub>c</sub>), 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<sub>s</sub>Ag, or other infectious agents are absent, it is recommended that **HemoPoint® H2 Hemoglobin Controls** be handled with the same precautions used for patient specimens.

**HemoPoint® H2 Hemoglobin Control** should be treated the same as a patient specimen and run in accordance with the instructions accompanying the instrument being used.

**HemoPoint® H2 Hemoglobin Controls** are 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 **HemoPoint® H2 Hemoglobin Control** appear to be grossly hemolyzed or appear to be visually clumped or aggregated, do not use. Contact 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

**HemoPoint® H2 Hemoglobin Controls** are a reliable liquid product manufactured under rigid quality control standards. To obtain good results, the product requires proper storage and handling as described.

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## Preparation

### For Information Use Only

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. Dispense a drop of control onto a clean non-absorbent material such as plastic film. Fill the microcuvette with the control as you would a patient sample.
4. Following the instrument manufacture's instructions for testing. Values should be read within 2 minutes after filling the sample into microcuvette.
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 vial immediately. After testing, return the vial to its proper storage.

## Limitations of the Procedure

1. **HemoPoint® H2** Hemoglobin Controls may not be appropriate for certain instruments other than the **HemoPoint® H2** Hemoglobin System.
2. Inaccuracies in test results may occur as a result of inappropriate mixing procedures. Precisely follow all mixing instructions before testing.

## Results

### For Information Use Only

An expected range is given for each level based on data generated from multiple lab analyses using the **HemoPoint® H2** Hemoglobin System. 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 Technical Service at (800) 531-5535.

| Control Values |                | Exp. Date: July 06    |
|----------------|----------------|-----------------------|
| <u>Level</u>   | <u>Lot No.</u> | <u>Expected Range</u> |
| Low            | 09751-3        | 5.2 - 6.4 g/dL        |
| Normal         | 09752-3        | 10.7 - 13.1 g/dL      |
| High           | 09753-3        | 14.8 - 18.2 g/dL      |

## Ordering Information

Catalog Number 3060-601 • **HemoPoint® H2** Hemoglobin Controls, 6 x 1.5mL (2 each Low, Normal and High Levels)  
Standing orders may be scheduled through Laboratory.

## For Information Use Only

CLIAwaived, Inc.  
SALES: Toll Free 1-888-882-7739  
e-mail: info@cliawaived.com  
http://www.cliawaived.com

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3. Remove the cap from the vial. Dispense a drop of control onto a clean non-absorbent material such as plastic film. Fill the microcuvette with the control as you would a patient sample.
4. Following the instrument manufacture's instructions for testing. Values should be read within 2 minutes after filling the sample into microcuvette.
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