



iFOBT Controls Set Instructions

<p style="text-align: center;">INTENDED USE</p> <p>Hemosure® iFOBT Controls includes a positive control containing stabilized human hemoglobin and negative control containing a buffer matrix. Hemosure® iFOBT Controls are for use exclusively with the Hemosure® iFOBT Test Kit.</p> <p>The controls can be used to independently verify the functionality and performance of the test; they are not for use as general-purpose controls.</p> <p style="text-align: center;">MATERIALS</p> <p>Materials Provided:</p> <ol style="list-style-type: none"> 1. Positive Control (5mL or 2mL) contains purified human hemoglobin, Tris buffer, bovine serum albumin, and 0.05% sodium azide. 2. Negative Control (5mL or 2mL) contains Tris buffer, bovine serum albumin, and 0.05% sodium azide. 	<p>Bovine materials are from a U.S. source.</p> <p>Materials Required but Not Provided:</p> <ol style="list-style-type: none"> 1. Hemosure® iFOBT Test Kit, Available separately. 2. Timer <p style="text-align: center;">PRECAUTIONS</p> <ol style="list-style-type: none"> 1. For <i>In Vitro</i> Diagnostic Use. 2. CAUTION: The Positive Control is prepared from material derived from human blood. The source materials are tested for the presence of antibodies to human immunodeficiency virus (HIV) and Hepatitis B Surface antigens (HBsAg) and found to be negative. However no test method can offer complete assurance that HIV, HBsAg, or other factious agents are absent; these reagents should be handled as potentially infectious. Such materials should be handled as bio-safety 	<p>Level 2, as defined by the U.S. Centers for Disease Control and Prevention.</p> <ol style="list-style-type: none"> 3. Avoid contamination of reagents; DO NOT interchange bottle caps between Positive and Negative Controls. 4. WARNING: The Positive and Negative Controls contain sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up. 5. Avoid contact with eyes, mucous membranes, skin lesions or other body surfaces. If contact occurs, flush affected areas with water for at least 10 to 15 minutes and immediately consult your physician. 6. DO NOT use controls beyond their labeled expiration dates. 7. DO NOT use any control from a container that appears to have leaked. 	<p style="text-align: center;">STORAGE</p> <ol style="list-style-type: none"> 1. Store product at 2°C-8°C. 2. When stored as directed, Hemosure® iFOBT Controls will remain stable until the labeled expiration date. <p style="text-align: center;">PROCEDURES</p> <ol style="list-style-type: none"> 1. Follow the Procedure in the Hemosure® iFOBT package insert. 2. When running Controls, add 3 drops of Positive or Negative Control to the sample pad using dropper bottles in place of samples. 3. Wait 5 minutes and read test results.
<p style="text-align: center;">INTERPRETATION OF TEST RESULTS</p> <ol style="list-style-type: none"> 1. The test is positive (+) if two lines (Control and Test) are visible in the viewing window. Any trace of a pink line in the Test line area is a positive test result. 2. The test is negative (-) if only the Control line is visible and there is no trace of a pink line in the Test line area. 3. The test is invalid if the control line does not appear, if this occurs, the test should be repeated. <p>Notes on Interpretation:</p> <ol style="list-style-type: none"> 1. Positive test results may appear before 5 minutes. To verify a negative test result, be certain to wait a full 5 minutes. 2. Test results should not be read after 10 minutes. 	<ol style="list-style-type: none"> 3. Neither the intensity nor the shade of the line produced by the Positive Control should be used as a reference for the appearance of a positive result. 4. If invalid results occur repeatedly or for technical assistance, contact Hemosure at: 1-888-436-6787 (Hemosure) <p style="text-align: center;">PERFORMANCE CHARACTERISTICS</p> <p>The Positive Control contains purified human hemoglobin and gives a positive result with Hemosure® iFOBT. The Negative Control contains a buffer and no human hemoglobin and gives a negative result with the Hemosure® iFOBT.</p> <p style="text-align: center;">PRODUCT INFORMATION</p> <p>Hemosure® iFOBT is CLIA Waived. Please visit www.hemosure.com for more information and product catalog.</p>	<p>Manufactured for:</p> <p>HEMOSURE, INC. 5358 Irwindale Avenue Irwindale, CA 91706</p> <p style="text-align: center;"> HEMOSURE, INC.</p>	<p style="text-align: right;">DGP35000-3.0</p>