

hema-screen *SPECIFIC* GOLD Hemoglobin Controls Positive & Negative Controls Product Instructions

External performance controls for Immunochemical
Fecal Occult Blood Test

INTENDED USE

hema-screen SPECIFIC GOLD Positive and Negative Hemoglobin Controls are intended for use as unassayed precision control material for the hema-screen SPECIFIC GOLD iFOBT product line. They can also be used as an external performance control material for *in vitro* diagnostic tests that qualitatively detect human hemoglobin in fecal samples. The controls can be used to independently verify the functionality and performance of the test.

MATERIALS

Materials Provided:

- Instructions for Use;
- Positive Control (3.0 mL), contains purified human hemoglobin, 0.09% sodium azide;
- Negative Control (3.0 mL), contains phosphate buffered saline, 0.09% sodium azide

Materials required but not provided:

- Timer

PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Read directions for use carefully before performing this test procedure.
- These are not intended to replace any controls supplied with a commercial kit.
- These are not intended to be used as a standard.
- 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 infectious agents are absent; these reagents should be handled as potentially infectious. Such materials should be handled at Biosafety Level 2, as defined by the U.S. Centers for Disease Control and Prevention.

- Avoid contamination of reagents; DO NOT interchange bottle caps between Positive and Negative Controls.
- 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.
- Avoid reagent 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.
- DO NOT use reagents beyond their labeled expiration dates.
- DO NOT use any reagents from a container that appears to have leaked.

STORAGE & STABILITY

Store product at room temperature up to 30°C; DO NOT FREEZE. When stored as directed, controls will remain stable until the labeled expiration date.

PROCEDURE

Note: Follow this Procedure & Interpretation of Results section when using this control kit with the hema-screen SPECIFIC GOLD product line. There is sufficient amount of positive and negative control material to perform twenty (20) tests.

1. When running controls, add three (3) drops of Positive or Negative Control into the test device well sample pad (in place of samples).
2. With test device lying flat on surface, read results within five (5) minutes after addition of control to the test device well.

INTERPRETATION OF RESULTS

- The test is POSITIVE (+) if two (2) lines (Test and Control) are visible in the results window within the test read time. One colored line appearing in the “T” area and another colored line appearing in the “C” area.
Note: Any trace of a line in the Test Line area is considered a positive test result.
- The test is NEGATIVE (-) if ONLY one (1) colored line appears in the Control Line area “C”; and there is no colored line appearing in the Test Line area “T”.
- The test is INVALID (INV) if the Control Line does not appear. If this occurs, the test should be repeated.

Notes on Interpretation:

- Positive test results may appear before 5 minutes. To verify a negative test result, be certain to wait a full 5 minutes.
- Test results should not be read after 5 minutes.
- 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.
- If invalid results occur repeatedly or for technical assistance, contact Immunostics, Inc. Technical Support at: (800) 722-7505.

PERFORMANCE CHARACTERISTICS

The Positive Control contains purified human hemoglobin and should test positive. The Negative Control contains a buffer and no human hemoglobin and should test negative. Each laboratory must establish complete quality control testing in accordance with the requirements of regulatory and/or accrediting organizations and the needs of the laboratory.

PRODUCT INFORMATION

Reorder Cat. №: HSGDCON

hema-screen SPECIFIC GOLD iFOBT is CLIA Waived.



Positive



Negative



Invalid



Invalid