

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k060463

**B. Purpose for Submission:**

Marketing test in the U.S.

**C. Measurand:**

Human Hemoglobin

**D. Type of Test:**

Qualitative, sandwich dye conjugate immunoassay

**E. Applicant:**

Immunostics, Inc.

**F. Proprietary and Established Names:**

hema-screen™ SPECIFIC

**G. Regulatory Information:**

1. Regulation section:

21 CFR § 864.6550, Occult Blood Test

2. Classification:

Class II

3. Product code:

KHE

4. Panel:

Hematology, 81

**H. Intended Use:**

1. Intended use(s):

The hema-screen™ SPECIFIC is for the rapid and qualitative determination of Human Blood fecal samples. It is intended for professional and laboratory use only. It is also useful for determining gastrointestinal bleeding due to a number of gastrointestinal (GI) disorders such as diverticulitis, colitis, polyps and colorectal cancer. This test is recommended for use in routine physical examinations, hospital monitoring of bleeding in patients, and for screening for colorectal cancer or gastrointestinal (GI) bleeding from any source.

2. Indication(s) for use:

Same as Intended Use.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

**I. Device Description:**

The hema-screen™ SPECIFIC FOB test kit consists of card type sampler, sampling bottles containing an extraction buffer and the immunochromatographic test in cassettes.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Alfa Scientific Instant-View™ FOBT

2. Predicate 510(k) number(s):

k021423

3. Comparison with predicate:

| Similarities   |  |           |
|----------------|--|-----------|
| Item           | Device   | Predicate |
| Test Principle | Immunoassay utilizing monoclonal and polyclonal antibodies for the detection of human hemoglobin | Same      |
| Cut-off        | 50 µg/hHb/gm feces   | Same      |
| Sample         | Feces in extraction buffer   | Same      |

| Differences       |  |                               |
|-------------------|--|-------------------------------|
| Item              | Device   | Predicate                     |
| Collection Method | Threaded wand and buffer tube or collection card and buffer tube | Threaded wand and buffer tube |

**K. Standard/Guidance Document Referenced (if applicable):**

“Review Criteria for the Qualitative Assessment of Fecal Occult Blood In Vitro Diagnostic Devices”

**L. Test Principle:**

Hema-Screen Specific is a chromatographic immunoassay (lateral flow device) for qualitative detection of human hemoglobin in fecal samples. The patient specimen is obtained using a wooden stick and Devel-A Tab (collection card), or fecal threaded wand collection device and added to the device’s extraction buffer bottle. The collection device/tube is gently shaken and the patient sample is added to the absorbent pad end of the device. The specimen migrates along a solid porous membrane matrix by capillary action, passing through three zones.

The first zone consists of mouse anti-human hemoglobin antibodies coated on colloidal gold particles. If human hemoglobin is present in the sample it will bind to the mouse anti-hHb coated gold particles and carry them along the solid porous membrane matrix.

The second zone contains polyclonal anti-hHb antibodies which have been fixed onto the membrane matrix. If the specimen is positive for human hemoglobin, it will deposit the hHb-anti hHb-colloidal gold complex at this site resulting in a red/purple band of color. Any red/purple color appearing in the “test zone” within the time specified on the package insert indicates a positive reaction. Absence of a colored line in this area is considered a negative reaction and indicates that the level of hHb in the specimen is less than the detectable level as specified on the package insert.

The third zone is the “Control Zone” and a red/purple line must appear in it to demonstrate that the device is functioning properly and validates the reaction in the “test zone”. Any unbound gold particles either due to a negative sample or in excess of that bound to the specimen will be deposited at this location as it is coated with goat anti-mouse IgG.

#### **M. Performance Characteristics (if/when applicable):**

##### **1. Analytical performance:**

##### **a. *Precision/Reproducibility:***

Twenty-five hemoglobin-free fecal samples were collected and spiked with human hemoglobin at the following concentrations: 0, 50 µg hHg/g (cutoff), and 2000 µg hHg/g.

#### **Inter Day Reproducibility Study**

| Sample               | Concentration/Results (µg hHb/g) |       |      |
|----------------------|----------------------------------|-------|------|
|                      | 0                                | 50.0  | 2000 |
| <b>Run 1</b>         |                                  |       |      |
| <b>Devel-A-Tab</b>   | 0/8                              | 10/10 | 7/7  |
| <b>Threaded Wand</b> | 0/8                              | 10/10 | 7/7  |
| <b>Run 2</b>         |                                  |       |      |
| <b>Devel-A-Tab</b>   | 0/8                              | 10/10 | 7/7  |
| <b>Threaded Wand</b> | 0/8                              | 10/10 | 7/7  |
| <b>Run 3</b>         |                                  |       |      |
| <b>Devel-A-Tab</b>   | 0/8                              | 10/10 | 7/7  |
| <b>Threaded Wand</b> | 0/8                              | 10/10 | 7/7  |

### Intra Day Reproducibility Study

| Sample               | Concentration/Results (µg hHb/g) |       |      |
|----------------------|----------------------------------|-------|------|
|                      | 0                                | 50.0  | 2000 |
| <b>Run 1</b>         |                                  |       |      |
| <b>Devel-A-Tab</b>   | 0/8                              | 10/10 | 7/7  |
| <b>Threaded Wand</b> | 0/8                              | 10/10 | 7/7  |
| <b>Run 2</b>         |                                  |       |      |
| <b>Devel-A-Tab</b>   | 0/8                              | 10/10 | 7/7  |
| <b>Threaded Wand</b> | 0/8                              | 10/10 | 7/7  |
| <b>Run 3</b>         |                                  |       |      |
| <b>Devel-A-Tab</b>   | 0/8                              | 10/10 | 7/7  |
| <b>Threaded Wand</b> | 0/8                              | 10/10 | 7/7  |

Lot to Lot reproducibility was determined by testing three production lots with spiking 50 fecal samples with varying levels of human hemoglobin. The following four levels were tested: 0, 37.5, 50, 62.5, and 2000 µg hHb/g feces. All three lots of devices yielded the same results 100% of the time.

*b. Linearity/assay reportable range:*

Not applicable

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Internal Control: Is built into the test strip and assures that the sample addition and migration through the test strip has occurred and that the control anti-mouse antibody and the reporter antibody are intact and functional.

*d. Detection limit:*

The minimal detectable concentration of hHb is 50 µg/hHb/gm feces or 50 ng/hHb/ml buffer.

*e. Analytical specificity:*

Animal Hemoglobin

The product was tested and found non-reactive in normal specimens spiked with beef hemoglobin (2000 µg/g), chicken hemoglobin (500 µg/g), fish hemoglobin (100 µg/g), horse hemoglobin (500 µg/g), goat hemoglobin (500 µg/g), pig hemoglobin (500 µg/g), rabbit hemoglobin (500 µg/g), sheep hemoglobin (100 µg/g). Nor was any interference noted when spiked into samples pre-spiked with 50 µg/g human hemoglobin.

Dietary Interference

Horseradish peroxidase (20 mg/mL), aqueous extracts or red radish, raw turnip, cauliflower, broccoli, parsnip, cantaloupe, and dietary supplements of

chloride, fluoride, multivitamins, Vitamin C (ascorbic acid) and iron were spiked into normal and positive (containing 50 µg hHg/g) fecal material. No interference with the expected results was observed.

*f. Assay cut-off:*

Same as limit of detection.

2. Comparison studies:

*a. Method comparison with predicate device:*

Method comparison performed at 3 POL and in-house showed 100% positive, negative, and overall agreement between hema-screen™ SPECIFIC and the predicate device.

*b. Matrix comparison:*

Not applicable.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not determined.

*b. Clinical specificity:*

Not determined.

*c. Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

4. Clinical cut-off:

Not determined.

5. Expected values/Reference range:

The expected value should be negative.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.