510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k100031

B. Purpose for Submission:
New device

C. Measurand:
Human Hemoglobin

D. Type of Test:
Qualitative Fecal Occult Blood

E. Applicant:
IND Diagnostic, Inc.

F. Proprietary and Established Names:
IND One Step Fecal Occult Blood (FOB) Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.6550, Occult Blood Test
2. Classification:
   Class II
3. Product code:
   KHE, Reagent Occult Blood
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The One Step Fecal Occult Blood (FOB) Test is a simple, direct binding immunoassay for the rapid and the qualitative detection of fecal occult blood by laboratories or physician's offices. It is useful to determine gastrointestinal bleeding found in gastrointestinal disorders. For professional *in vitro* diagnostic use only.
2. Indication(s) for use:
   Not applicable.
3. Special conditions for use statement(s):
   Prescription use only.
4. Special instrument requirements:
   Not applicable.

I. Device Description:
The One Step Fecal Occult Blood (FOB) Test consists of a sampling bottle containing an extraction buffer and an immunochromatographic test for human hemoglobin in a cassette.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Immunostics, Inc. hema-screen™ SPECIFIC
   WHPM, Inc. Hemosure™ One-Step Fecal Occult Blood (FOB) Test
2. Predicate 510(k) number(s):

k060463
k041202

3. Comparison with predicates:

Similarities			
Item	Device	Predicate (k060463)	Predicate (k041202)
Intended Use	The One Step Fecal Occult Blood (FOB) Test is a simple, direct binding immunoassay for the rapid and the qualitative detection of fecal occult blood by laboratories or physician's offices. It is useful to determine gastrointestinal bleeding found in gastrointestinal disorders For professional *in vitro* diagnostic use only.	The Hema-Screen™ Specific is for the rapid and qualitative determination of Human Blood in 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 cancer. This test is recommended for use in routine physical exams, hospital monitoring of bleeding in patients and for screening for colorectal cancer of gastrointestinal (GI) bleeding from any source.	The Hemosure™ One-Step Fecal Occult Blood (FOB) Test is an immunochemical device intended for the qualitative detection of Fecal Occult Blood by laboratories or physicians offices. It is useful to determine gastrointestinal (GI) bleeding found in a number of GI disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer.
Detection Limit	50 ng/mL of human hemoglobin in fecal extraction buffer	Same	Same
Technology	One-step sandwich immunoassay	Same	Same
Antibodies	Polyclonal and monoclonal (anti-human hemoglobin and goat anti-mouse IgG)	Same	Same

Differences			
Item	Device	Predicate (k060463)	Predicate (k041202)
Buffer Composition	Saline buffer containing 0.85% NaCl	PBS with 0.5 NaN_3	0.01 M Phosphate Buffer

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

Not applicable.

L. Test Principle:

The IND One Step Fecal Occult Blood Test is a qualitative sandwich immunoassay test designed for the determination of occult blood (human hemoglobin (hHb)) in

fecal samples. The device consists of a test cassette with a pad containing anti-Hb antibodies conjugated to colloidal gold, a nitrocellulose strip containing a test line which contains monoclonal anti-hHb antibodies; and a control line of monoclonal and polyclonal anti-mouse IgG antibodies. As the test sample migrates, via capillary action, through the absorbent test strip, a labeled antibody-dye conjugate binds to hHb if present in the specimen.

In the presence of hHb ≥ 50 ng/mL, the labeled antibody-antigen dyed complex will form; bind to the anti-hHb antibody in the positive test region and produce a color band indicating a positive result. In the absence of hHb, no line is produced in the positive test region indicating a negative result.

Each test cassette has an internal control region. The control region binds the conjugated mouse antibodies regardless of the hHB concentration. A color band in the control region demonstrates that the reagents are functioning properly. If there is no band in the control region then the test has malfunctioned and needs to be redone with another cassette.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     The IND One-Step FOB Test was tested at three (3) physician health lab clinics (POL) in the U.S and in-house. At each site, a total of 100 artificial stool samples were spiked with human hemoglobin at 0, 37.5, 50, 62.5, and 2000 ng/mL in extraction buffer. In the POL environment, at site 1 there was 98% agreement, at site 2 there was 95% agreement and at site 3 there was 99% agreement with the expected results. For in-house testing, the agreement was 99% with the expected results.
   - *b. Linearity/assay reportable range:*
     Not applicable.
   - *c. Traceability, Stability, Expected values (controls, calibrators, or methods):*
     Stability: Three lots of the extraction buffer with and without hHB in feces were tested at 4°C and found to be stable for at least 7 days.
     Three lots of the test cassette were tested at room temperature (20-25°C) and found to be stable for 12 months.
     Internal Control: Procedural controls are included in the test device. A magenta line appearing the control region is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
     External Control: Controls are not provided with this kit. Positive and negative controls were bought commercially from Sigma Aldrich. The concentration of negative control is (0, 37.5 ng/mL) and the concentration for positive control is (50, 62.5, 2000 ng/mL). It is recommended that positive and negative controls be performed to verify proper test performance.
   - *d. Detection limit:*
     The minimal detection limit is 50 ng/mL of hHb in fecal extraction buffer.
   - *e. Analytical specificity:*
     Positive (50 ng/mL hHb in fecal extraction buffer) and negative (0 ng/mL hHb in fecal extraction buffer) samples were spiked with the following

substances: beef, chicken, fish, horse, goat, pig, rabbit, and sheep hemoglobin, horseradish, red radish, turnip, broccoli, parsnip, cantaloupe, horseradish peroxidase, Vitamin C and iron. Addition of these substances had no effect on the test results.

f. Assay cut-off:
The assay cut-off is 50 ng/mL of hHb in buffer.

2. Comparison studies:
   a. Method comparison with predicate device:
   At an in-house laboratory, a fecal occult blood test with known clinical outcomes (Beckman Coulter Hemoccult-ICT) was used to compare with the IND Diagnostic One-Step FOB Test kit in 20 stool samples spiked with hHb at each of the following concentrations: 0, 37.5, 50, 62.5, and 2000 ng/mL, for a total of 100 samples.
   The overall agreement was 98% (98/100) with corresponding 95% CI (97.8%-98.2%), the positive percent agreement was 98.3% (59/60) with corresponding 95% CI (98.1%-98.5%) and the negative percent agreement was 97.6% (40/41) with corresponding 95% CI (97.3%-97.8%).
   b. Matrix comparison:
   Not applicable.
3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable.
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Results are negative when <50 ng/mL of hHb in buffer and positive when ≥ 50 ng/mL of hHb in buffer.

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.