**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K060953

B. Purpose for Submission:

Marketing in the U.S.

C. Measurand:

Human Hemoglobin

D. Type of Test:
Immunological test for the qualitative detection of monoclonal antibodies for human hemoglobin

E. Applicant:

YD Diagnostics Corporation

F. Proprietary and Established Names:

OcculTech Fecal Occult Blood Rapid Test

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 OcculTech Fecal Occult Blood Rapid test is a card type rapid test and an immunochromatographic based *in-vitro* test designed for qualitative detection of fecal occult blood that can be performed in laboratories or physician's offices. It is useful in determining gastrointestinal bleeding found in a number of gastrointestinal disorders (e.g., diverticulitis, colitis, polyps and colorectal cancer).

2. Indication(s) for use:

   This device is recommended for use in routine physical examinations, when hospital patients are first admitted, hospital monitoring for bleeding in patients, and screening for colorectal cancer or gastrointestinal bleeding from any source.

3. Special conditions for use statement(s):

   N/A

4. Special instrument requirements:

   N/A

I. Device Description:

The device is composed of a single test strip enclosed in a plastic case which has a sample hole and a test result window on the same side. The test strip has three sections: the lower wick is made of the sample and conjugate pad; the test area consists of white nitrocellulose membrane immobilized with monoclonal anti-hemoglobin IgG, which is located on the center of the strip; and the absorption pad on the upper wick. Specimen is collected on a grooved sample stick and placed in a specimen collection tube containing an extraction buffer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Alfa Scientific, Inc. Instant-View™ Fecal Occult Blood Test

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

   K021423

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample	Feces in extraction buffer	Same
Intended Use	Qualitative detection of fecal occult blood in feces by professional laboratories and physician's offices	Same
Sensitivity	50 ng hHb/ml buffer	Same

Differences		
Item	Device	Predicate
Extraction Buffer	Tris Buffer	PBS Buffer

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

L. Test Principle:

The OcculTech Fecal Occult Blood Rapid Test is a colloidal gold enhanced immunoassay for the detection of hemoglobin in human stool. The stool is collected into a sample collection tube containing a buffer. The extracted stool sample in buffer is then dropped onto the sample pad of the test device and migrates by capillary action through the test zone. If the specimen contains hemoglobin an antigen-antibody complex forms with the monoclonal anti-hemoglobin IgG gold colloid conjugate in the conjugate pad. The mixture migrates to the nitrocellulose membrane in the test region where an immobilized monoclonal anti-hemoglobin IgG forms a sandwich binding if hemoglobin is present. The captured dye-complex becomes visible as a colored line within the test zone, which indicates the test has detected human hemoglobin. In the absence of hemoglobin no line is formed in the test zone.

A procedural control is built into the test device to indicate proper test performance. It appears as a rose-pink sandwich dye conjugate reaction and should appear regardless of the test result.

A rose-pink band in the test zone and in the control zone at or before five minutes is considered a positive result by the criteria of the test. A band only in the control zone at five minutes is a negative result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   40 human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 2000 ng/ml. 8 samples were tested at each concentration with three lots of the OcculTech FOBT and the predicate device. Samples with concentrations below 50 ng/ml hHb tested negative with the candidate and predicate device while samples at and above 50 ng/ml tested positive.

   b. *Linearity/assay reportable range:*
   N/A

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

   Internal Control: A procedural control is built into the test device to indicate proper test performance. It appears as a rose-pink sandwich dye conjugate reaction and should appear regardless of the test result.

   External Control: Positive and negative controls should be run to insure that the captured and conjugated antibodies are present and reactive.

   d. *Detection limit:*
   The minimal detectable concentration of hHb is 50 ng/ml in buffer or 5ug/g in feces.

   e. *Analytical specificity:*
   Cross Reactivity
   This FOB test is specific to human hemoglobin. The following substances when spiked in both positive and negative specimens did not interfere with the test results.

Substance	Concentration (ug/ml)
Chicken Hb	500 ug/ml
Pig Hb	500 ug/ml
Horse Hb	500 ug/ml
Beef Hb	2000 ug/ml
Rabbit Hb	200 ug/ml
Goat Hb	500 ug/ml
Fish Hb	Meat extract
Sheep Hb	Meat extract

<u>Dietary Interference</u>

Aqueous extracts of horseradish peroxidase, red radish, raw turnip, cauliflower, broccoli, parsnip, cantaloupe, and ascorbic acid, iron and human serum albumin were tested with and without hHb by OcculTech FOBT and the predicate device. All tests were negative when hHb was absent and positive when hHb was present.

f. Assay cut-off:

N/A

2. <u>Comparison studies:</u>

a. Method comparison with predicate device:

One hundred human hemoglobin free stool extraction specimens were collected and divided into 5 groups of 20. The 5 groups were spiked with hHb in the following concentrations: 0, 37.5, 50, 62.5, and 2000 ng/mL. The specimens were tested by three professionals at physician offices with diverse educational backgrounds and work experiences and at a reference laboratory using both the OcculTech FOBT and the predicate device.

The results of the POL tests agreed 98% with expected results. The results obtained from the reference laboratory agreed 99% with the expected results. There was 99% agreement between the OcculTech FOBT and the predicate device.

b. Matrix comparison:

N/A

3. <u>Clinical studies:</u>

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

4. <u>Clinical cut-off</u>**:**

5. <u>Expected values/Reference range:</u>

N. Proposed Labeling:

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

O. Conclusion:

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