

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

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

K071242

**B. Purpose for Submission:**

Marketing in the U.S.

**C. Analyte:**

Human Hemoglobin

**D. Type of Test:**

Fecal Occult Blood

**E. Applicant:**

AmeriTek USA, Inc.

**F. Proprietary and Established Names:**

dBest One Step Occult Blood (OB) Test Kit

**G. Regulatory Information:**

1. Regulation section:  
864.6550 Occult blood test
2. Classification:  
Class II
3. Product Code:  
KHE
4. Panel:  
Hematology (81)

**H. Intended Use:**

1. Intended use(s):  
dBest One Step Occult Blood Test Kit is a simple immunochromatographic assay for rapid, qualitative detection of fecal occult blood for laboratories or physician's offices.
2. Indication(s) for use:  
It is useful as a diagnostic test kit to aid in detection of bleeding caused by a number of gastrointestinal disorders, such as diverticulitis, colitis, polyps and colorectal cancer. dBest One Step Occult Blood Test Kit is recommended for use in 1) Routine physical examinations, 2) Hospital monitoring for gastrointestinal bleeding and 3) Screening for colorectal cancer.
3. Special condition for use statement(s):  
For professional use only.
4. Special instrument Requirements:  
N/A

**I. Device Description:**

The dBest One Step Occult Blood Test consists of a sampling bottles containing an extraction buffer and an immunochromatographic test for human hemoglobin in a cassette.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
AlfaScientific Instant View FOBT
2. Predicate K number(s):  
K021423
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended use	Qualitative detection of occult blood in feces	Same
Format	Cassette	Same
Detection method	Immunochromatographic assay	Same
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Cut-off	10 ng/ml blood in feces	50 ng/ml blood in feces

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

N/A

**L. Test Principle:**

This test kit is a one-step lateral flow chromatographic immunoassay. The test consists of (1) a burgundy colored conjugate pad containing mouse anti-hHb antibodies conjugated with colloidal gold and (2) a nitrocellulose membrane containing a Test line: a0hHb-line appears as a visible burgundy line, if the concentration of hHb in the specimen is at or above 10 ng/ml blood in feces.

A fecal sample is collected and prepared for testing using the fecal collection tube and then added directly to the test device. The sample fluid mixes with anti-hHb-dye-conjugate in the test membrane forming an anti-hHb antigen-dye-complex, which migrates through the test device. Fecal traces now in the form of an antibody-complex are captured in the test zone by immobilized anti-hHb antibodies. The captured dye-complex becomes visible as a purple band, which indicates the test has detected hHb as a positive result. In the absence of broken red cells, no line of hHb in the test zone.

The Control Line is used for building in procedural control. Goat or rabbit-anti-mouse IgG or goat anti-rabbit IgG is used for the control line coating. When the gold conjugate reagent flows to the control line area, the goat or rabbit anti-mouse igG or goat anti-rabbit IgG will react with gold conjugate and develop the purple color regardless whether the sample contains hHb or not. This built-in control line indicates the test has worked properly.

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

1. Analytical performance:
  - a. *Precision/Reproducibility:*

Reproducibility of the Forsure One Step FOB Screen Card Test was determined using replicate samples of extraction buffer spiked with human hemoglobin in the following concentrations: 0, 25, 50, 75, 200 and 2000 ng/ml. Fifteen tests per concentration were tested by one technician in one day and all results were as expected. Three different lots were tested over 15 days by three different technicians. All results were as expected.

*b. Linearity/assay reportable range:*

N/A

*c. Traceability (controls, calibrators, or method):*

Internal Control: Procedural controls are included in the test device. A magenta line appearing the control region is considered as internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Control: Controls are not provided with this kit. It is recommended that positive and negative controls be performed to verify proper test performance.

*d. Detection limit:*

The minimal detection limit is 10 ng/ml of hHb in stool.

*e. Analytical specificity:*

Positive and negative stool samples were spiked with the following substances: Beef, chicken, horse, goat, pork, and rabbit hemoglobin; horseradish peroxidase; red radish; raw turnip; cauliflower; broccoli; parsnip; cantaloupe. Addition of these substances had no effect on the test results. Neither hemoglobin nor myoglobin of fish or sheep has been tested for potential false positive results.

Potential interfering chemicals such as pain medication, protein and glucose were supplemented to normal fecal specimens devoid of hemoglobin. Baseline fecal level, as well as 25 ng/gm hemoglobin were then analyzed in parallel with all samples containing a specific concentration of an interfering substance. Baseline fecal samples with supplementation with potentially interfering substances gave consistently negative test results and 25ng/gm hemoglobin substances scored consistently positive.

*f. Assay cut-off:*

N/A

2. Comparison studies:

*a. Method comparison with predicate device:*

(See clinical studies below)

### **Reference Laboratory and Physicians Office (POL) Study**

One hundred (100) hHb-free feces extraction specimens collected in-house were divided into 5 groups of 20 each. The five groups of extraction samples were spiked with hHb for five different concentrations, respectively; 0, 7.5, 10, 12.5 and 2000 ng hHb/ml. The above specimens were blind labeled and tested with dBest OB at three Physicians Offices and a Reference Laboratory.

The results obtained from three POL sites by persons with diverse education background and work experiences agreed 98% with expected results. Two samples at cut-off level were reported as negative in the POL sites. The results obtained from the Reference Laboratory agreed 99% with that expected. One sample at cut-off level was reported as negative. The cut-off level is 10 ng/ml of hHb/ml. The test of samples at 0, 7.25, 12.5 and 2000 ng/ml of hHG were all reported correctly.

*b. Matrix comparison:*

### 3. Clinical studies:

*a. Clinical sensitivity:*

#### **Clinical Sensitivity in a High Risk Population**

The performance of dBest OBT and the predicate device was assessed in a high-risk population of 120 individuals with a personal or family history of colorectal cancer and/or physical signs or symptoms suggestive of lower gastrointestinal disorders scheduled for colonoscopy. All patients were evaluated by colonoscopy and/or biopsy. A comparison of the dBest OBT and the predicate device versus the clinical diagnosis was performed.

#### **High Risk Population Study dBest OBT and Alfa Scientific vs. Clinical Pathology**

	dBest OBT	Predicate
<b>Clinical Sensitivity</b>		
Colorectal neoplasia*	89.5% (17/19) (68.6% - 97.1%)	78.95% (15/19) (56.7% - 91.5%)
Colorectal Cancer	93.5% (15/16) (71.7%- 98.9%)	87.5% (14/16) (64%- 96.5%)
Adenomas $\geq$ 1 cm	66.67% (2/3) (20.76% - 93.86%)	33.3% (1/3) (6.14 - 79.2%)
Adenomas < 1 cm	83.87% (26/31) (67.37 - 92.91%)	16.13% (5/31) (7.09% - 32.63%)
Hyperplastic polyps	72.13% (44/61) (59.83% - 81.8%)	59.02% (36/61) (46.5% - 70.5 %)
Specificity (no evidence of disease)	55% (5/9) 26.7% - 81.12%)	88.9% (8/9) (56.5% - 98.1%)
Specificity for	94.1% (111/118)	100% (118/118)

colorectal neoplasia (88.3%-97.1%) (96.7%-100%)

*b. Clinical specificity:*

**Specificity Study (Target age normal study)**

A group of 120 asymptomatic persons over the age of 40 years were tested with the dBest One Step OBТ and the predicate device. No dietary restrictions were followed. All patients were followed with colonoscopy and/or biopsy. The specificity of dBest One Step OBТ was 98.2% (2/112) (93.72% - 99.51%) and the predicate was 100% (0/112) (96.68% - 100.00%).

**Average Risk Screening Study**

**dBest OBТ and Alfa Scientific vs. Clinical Pathology**

	dBest OBТ	Predicate
Test Positivity Rate	6.7% (8/120)	0% (0/120)
Positive Predictive Value for adenomas $\geq$ 1 cm	12.5% (1/8)	0% (0/8)
Adenomas < 1 cm	62.5% (5/8)	0% (0/8)
Sensitivity for any size adenomas	75% (6/8)	0% (0/8)
Adenomas $\geq$ 1 cm	50% (1/2)	0% (0/2)
Adenomas < 1 cm	83.3% (5/6)	0% (0/6)
Any size adenomas	75% (6/8)	0% (0/8)
False Positive Rate (no pathology found)	1.78% (2/112)	0% (0/112)
Specificity (no evidence of disease)	98.21% (110/112) (93.7%-99.5%)	100% (112/112) (96.68-100%)
Specificity for Colorectal Neoplasia*	26.7% (27/101) (19.1%-36.1%)	58.4% (59/101) (48.7%-67.5%)

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

4. Clinical cut-off:

Among high risk patients, the dBest One Step Occult Blood Test showed high sensitivity for colorectal cancer and larger polyps, that if detected and removed early might prevent cancer from developing. This was the expense of a lower specificity for colorectal cancer and large adenomas, both in average risk and high risk individuals. Clinicians and patients should weigh the potential risks and benefits of the lower cut-off for positive results in their testing programs.

5. Expected values/Reference range:

**N. Conclusion:**

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

