

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

A. 510(k) Number:

k100817

B. Purpose for Submission:

New Device

C. Measurand:

Human Hemoglobin (hHb) in human feces

D. Type of Test:

Qualitative

E. Applicant:

Princeton BioMeditech Corporation

F. Proprietary and Established Names:

BioSign® iFOBTtest

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):
BioSign® iFOBTtest is a rapid qualitative test for the immunochemical detection of fecal occult blood/human hemoglobin (hHb) in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders such as: diverticulitis, colitis, polyps, and colorectal cancer. The device is suitable for use in laboratories and physician's offices as well as for home use.
2. Indication(s) for use:
The test is recommended for use in routine physical examination, new patient screening at admission and screening and monitoring any suspected colorectal cancer and/or gastrointestinal bleeding from any source.
3. Special conditions for use statement(s):
Prescription and Over-the-counter use
4. Special instrument requirements:
Not applicable

I. Device Description:

The BioSign® iFOBTtest device consists of a sample well and a testing pad that employs solid-phase chromatographic immunoassay technology to detect the presence of FOB in human feces. The sample is collected in a tube with extraction buffer.

J. Substantial Equivalence Information:

1. Predicate device name(s):
QuickVue® iFOB test
2. Predicate 510(k) number(s):
k070660
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Qualitative detection of occult blood in feces	Same
Sample Type	Feces	Same
Assay	Lateral flow chromatographic immunoassay	Same
Detection Level	50 ng/mL hHb in fecal extraction buffer	Same
Users	Healthcare professionals and lay persons (OTC)	Healthcare professional use and lay persons (OTC)
Differences		
Item	Device	Predicate
Format	Cassette only	<u>Dip Strip and Cassette</u>

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

N/A

L. Test Principle:

The BioSign® iFOBTest is a rapid qualitative test detecting the presence of human hemoglobin (hHb) in a fecal sample at 50 ng/mL and above. The tube is shaken to mix the fecal sample in the extraction buffer. Then, 3 drops (about 110 µL) of the mixed sample solution is added onto the sample well of the test device. After the sample has been dispensed into the sample well, the extracted sample migrates into the pad containing detector antibody conjugated dye label. The hHb in the sample will bind to the detector antibody and migrate onto the membrane where the test and control lines are located. On the membrane, immobilized capture antibodies form the invisible Test line. When the complex of hHb and detector antibodies reaches the Test line, the complex binds to the capture antibodies to form a visible reddish Test line indicative of a positive result; i.e., hHb is present. When no hHb is present in the sample, no reddish Test line forms. In addition to the Test line, a Control line on the membrane provides an internal quality control of the test device. Anti-species specific IgG antibodies are immobilized at the Control line. These antibodies will capture any unreacted/excess antibody-gold conjugates, forming a distinct Control line. The Control line serves to demonstrate that: lyophilized antibodies in the dye pad have been hydrated; sufficient sample has been applied to allow for migration to the Test line and beyond; chemicals are working properly; and the proper procedure

was followed. If a Control line does not appear within the designated incubation time, the test result is invalid and the test should be repeated using a new test device.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/ml. Eight samples were tested at each concentration with two lots of the BioSign iFOB test. Samples with concentrations below 50 ng/ml hHb tested negative with the candidate device while samples at and above 50 ng/ml tested positive, as expected.

b. *Linearity/assay reportable range*

Not applicable

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

Internal Control: Procedural controls are included in the test device. A reddish 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 50 ng/mL of hHb in buffer or 50µg hHb/g in stool.

e. *Analytical specificity:*

Positive and negative stool samples were spiked with the following substances: beet, chicken, fish (meat extract), horse, goat, pig, rabbit, and sheep hemoglobin, horseradish peroxidase, red radish, raw turnip, cauliflower, broccoli, parsnip, cantaloupe, Vitamin C and iron. Addition of these substances had no effect on the test results.

g. *Assay cut-off:*

The assay cut-off is 50 ng/mL of hHb in buffer or 50µg hHb/g in stool.

2. Comparison studies:

a. *Method comparison with predicate device:*

The BioSign iFOBT test was evaluated in comparison with a commercially available predicate device in a reference laboratory study. Five (5) different sample concentrations, 0, 37.5, 50, 62.5, and 500 ng hHb/mL, were tested using the BioSign iFOBT test device and the predicate device using 8 replicates for each concentration, for a total of 40 samples. At each concentration, all results with the BioSign iFOBT test agreed 100% with expected results and the results of the predicate.

The BioSign® iFOBT test was also evaluated in a study at three physicians' office laboratory (POL) sites. Five (5) different concentrations, 0, 37.5, 50, 62.5, and 500 ng hHb/mL, were prepared by spiking hHb into the extraction buffer. Each concentration was divided into 60 vials for each test. These vials were labeled for blind study. Each site tested a total of 100 tests with blinded samples of 5 concentrations, 20 samples per concentration, for a total

of 300 samples. The results obtained from the three POL sites agreed 99.7% with the expected results.

Therefore, the overall agreement of the BioSign® iFOBTest with the expected results is 99.7%.

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 \geq 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 substantial equivalence decision.