

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

A. 510(k) Number:

K063673

B. Purpose for Submission:

Marketing Product in U.S.

C. Measurand:

Human Hemoglobin

D. Type of Test:

Fecal Occult Blood

E. Applicant:

Innovacon, Inc.

F. Proprietary and Established Names:

Innovacon Flipcard™ Fecal Occult Blood Test

G. Regulatory Information:

1. Regulation section:

21 CFR 864.6550

2. Classification:

Class II

3. Product code:

KHE-Reagent Occult Blood

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

The Innovacon Flipcard™ Fecal Occult Blood Test Device is intended for rapid qualitative detection of human hemoglobin in fecal samples. Fecal occult blood tests are used as a screening tool for detecting lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, peptic ulcer, ulcerative colitis, polyp and colorectal cancer.

2. Indication(s) for use:

The Flipcard™ FOBT is recommended for use by health professionals in routine physical examinations and in monitoring for GI bleeding in patients in hospitals or at physician's offices.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

I. Device Description:

The Innovacon Flipcard™ Fecal Occult Blood Test Device is a rapid test intended for the qualitative detection of low levels of fecal occult blood. The test uses a double antibody sandwich assay to selectively detect fecal occult blood at 50 ng hHb/mL buffer or 300 µg hHB/g feces.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Beckman Coulter Hemocult® ICT Immunochemical Fecal Occult Blood Test

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

K961062

3. Comparison with predicate:

Similarities		
Item	Device	Predicate

Similarities		
Item	Device	Predicate
Test Principle	Immunoassay lateral flow test strip system for the detection of human hemoglobin	Same
Collection Method	Collection Card	Same
Buffer	PBS	Same

Differences		
Item	Device	Predicate
Antibody Type	Monoclonal Antibody	Polyclonal Antibody

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

L. Test Principle:

The Flipcard FOB Test Device is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane to generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Intra-Assay: Using three different lots, three spiked positive samples and three negative samples were tested with the same lot in replicates of 10, for a total of 180 tests. Results were read as positive or negative as specified in the package insert. Sample results were correct and in agreement for each of the 18 samples.

Inter-Assay: Ten different negative and ten different positive samples were tested on three lots. Results were read as positive or negative as specified in the package insert. All three lots yielded correct results and were in

agreement for each of the samples.

b. Linearity/assay reportable range:

The candidate device detected blood at levels up to 100 ml whole blood per 100 g feces.

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

Internal (Procedural) Control: Is included in the device. A colored line appearing in the Control line region (C) indicates that adequate sample volume and reagents were used and both have migrated properly. If the C-line does not form the test is considered invalid and the test should be repeated.

External Controls: The positive and negative external controls should be run every 25 tests. External Positive and Negative Controls are supplied in the kit.

d. Detection limit:

The analytical cut-off for the Flipcard™ FOB test is 50 ng hHb/mL buffer or 300 µg hHb/g feces.

e. Analytical specificity:

Studies were done to investigate the cross reactivity of the Flipcard™ FOB test. Diluted extracts of the following substances were added to positive and negative controls. No cross reactivity was observed.

Substance	Concentration
Bovine hemoglobin	1 mg/mL buffer
Chicken blood (1:10 in buffer)	0.1 mL/g feces
Pork hemoglobin	1 mg/mL buffer
Goat blood (1:10 in buffer)	0.1 mL/g feces
Horse hemoglobin	1 mg/mL buffer
Rabbit hemoglobin	1 mg/mL buffer
Fish blood (1:10 in buffer)	0.1 mL/g feces
Pork extraction (Fresh/boiled)	1 mL/g feces
Beef extraction (Fresh/boiled)	1 mL/g feces
Chicken extraction (Fresh/boiled)	1 mL/g feces
Goat extraction (Fresh/boiled)	1 mL/g feces
Fish extraction (Fresh/boiled)	1 mL/g feces
Cabbage extraction (Fresh/boiled)	1 mL/g feces

Red radish extraction (Fresh/boiled)	1 mL/g feces
Cauliflower extraction (Fresh/boiled)	1 mL/g feces
Cantaloupe extraction (Fresh/boiled)	1 mL/g feces
Iron (Fe ²⁺ /Fe ³⁺)	5 mg/mL buffer

f. Assay cut-off:

g. Other supportive data:

Physician Office Lab (POL) Studies:

Additional studies were conducted at three POLs and performed by personnel with various educational backgrounds. Each office tested a randomly coded panel of samples. Ninety hemoglobin free stool extracts were collected and separated in 5 groups of 18. Each group of samples were spiked with a known level of human hemoglobin to result in the following concentrations: 0 µg hHb/g feces, 100 µg hHb/g feces, 225 µg hHb/g feces, 375 µg hHb/g feces, and 450 µg hHb/g feces. There was an 89% correlation with expected results. (95% CI 84-92%).

2. Comparison studies:

a. Method comparison with predicate device:

The Flipcard FOB Test Device has been compared with the predicate device at two sites using both human hemoglobin spiked occult blood negative samples and hemoglobin positive patient samples.

Method		Predicate Device		Total
Flipcard FOB Test	Results	+	-	
	+	48	3	51
	-	2	215	217
Total		50	218	268

Positive Percent Agreement: 96% (46/50) (95% CI 86-99.5%)

Negative Percent Agreement: 98.6% (215/218) (95% CI 96.0-99.7%)

Total Agreement: 98.1% (263/268) (95% CI 95.7-99.4%)

b. Matrix comparison:

N/A

3. Clinical studies:

a. *Clinical Sensitivity:*

N/A

b. *Clinical specificity:*

N/A

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

4. Clinical cut-off:

5. Expected values/Reference range:

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.