

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

A. 510(k) Number:

k132167

B. Purpose for Submission:

Clearance of *i*-CHROMA iFOB with *i*-CHROMA Reader and *i*-CHROMA iFOB Controls

C. Measurand:

Human hemoglobin (hHb) in feces

D. Type of Test:

Fluorescence immuno-chromatographic

E. Applicant:

Boditech Med Inc.

F. Proprietary and Established Names:

i-CHROMA iFOB with *i*-CHROMA Reader
i-CHROMA iFOB Controls

G. Regulatory Information:

1. Regulation section:

21 CFR 864.6550, Occult blood test

21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class II for device

Class I for controls

3. Product code:

OOX, Automated occult blood analyzer

JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:

Hematology (81)
Chemistry (75)

H. Intended Use:

1. Intended use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an in vitro diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

i-CHROMA iFOB Controls are the quality control reagents intended for monitoring and ensuring acceptable performance of *i*-CHROMA iFOB test system which is a qualitative in vitro diagnostic test for detection of fecal occult blood having a lower analytical detection limit of 25 ng/mL and the cut-off of 100 ng/mL (hemoglobin in human fecal samples)

2. Indication(s) for use:

Same as Intended use.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

i-CHROMA Reader

I. Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA™ Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

1. Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer'.

- a. The *i*-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing. Test strip components include a nitrocellulose membrane of which, murine antibodies against human hemoglobin have been immobilized at the test line and rabbit immunoglobulin-G at the control line, a sample pad, an absorption pad and a plastic backing. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed

test cartridges are packed in a box which also contains an ID chip.

- b. The ID chip contains a memory device with encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.
- c. The *i*-CHROMA iFOB Sample Collection Tube is a specially designed plastic container. Each sample collection tube contains 1mL detection buffer. The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each kit contains 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube acts as the common mechanism for the following:

- i. Proper sampling of the fecal sample.
 - ii. Processing or thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample.
 - iii. Application of precise quantity of the processed fecal sample into the ‘Sample well’ of the *i*-CHROMA iFOB test cartridge.
- d. A ‘Patient Pack’ is provided along with the test cartridge box and may also be purchased separately. Each ‘Patient Pack’ contains following items:
 - i. 1 Patient Instructions Leaflet (for sampling instructions)
 - ii. 1 Sample Collection Paper (for fixing onto the toilet bowl)
 - iii. 1 Sample Sac (for enclosing the sample collection tube after sampling)
 - iv. 1 Return Envelope (for submitting the sample collection tube to the laboratory/physician’s office for testing)

2. *i*-CHROMA iFOB Controls

i-CHROMA iFOB Controls consisted of a negative and a positive control with different levels of human hemoglobin A₀ in buffered liquid medium with preservatives. The assigned target values (acceptable ranges) for the negative and positive controls are 50 ng/mL (45-55 ng/mL) and 50 ng/mL (135-165 ng/mL) respectively.

3. *i*-CHROMA Reader:

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; processed and tested by *i*-CHROMA iFOB. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed and supplied separately.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):

OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer, k041408

2. Comparison with predicate:

Similarities		
Item	Device <i>i</i> -CHROMA iFOB with <i>i</i> -CHROMA Reader	Predicate OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer
Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices.	Qualitative detection of fecal occult blood in feces by professional laboratories.
Indications for Use	Routine physical examination, screening when gastrointestinal bleeding disorders may be suspected.	(1) Routine physical examinations, (2) Monitoring for bleeding in patients, and (3) Screening for colorectal cancer or gastrointestinal bleeding.
User(s)	Laboratories and physician offices.	Professional laboratories.
Test Sample	Human fecal sample mixed with the detection buffer in a collection tube.	Feces in an extraction buffer.
Test Principle	Immunological test system based on antigen-antibody fluorescence technology for qualitative detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces.
Sampling and Sample Processing	Sampling is done with the help of the Sampling Stick/Sampler which is part of the sample collection tube. The fecal sample is delivered into the sample collection tube containing the detection buffer which extracts it.	Sampling is done with the help of the Sampling Probe which is a part of the OC-Auto Sampling Bottle. The fecal sample is delivered into the sampling bottle containing the buffer which extracts it.
Assay Cut-off	100 ng/mL (Human hemoglobin in human fecal sample mixed with detection buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
Presentation of Test Results	Qualitative (Positive or Negative)	Qualitative (Positive or Negative)

Differences		
Item	Device <i>i</i> -CHROMA iFOB with <i>i</i> -CHROMA Reader	Predicate OC Auto Micro FOB Test with Polymedco OC Auto Micro 80Analyzer
Test Platform	Lateral flow chromatographic fluorescence immunoassay.	Automated immunoassay using latex fixation.
Test Time	10 minutes	5~10 minutes
Detection Mechanism	Scanning/measurement of intensity of fluorescence on the processed sample-loaded test cartridge membrane.	Optical measurement of agglutination of latex particles.

Differences		
Item	Device <i>i</i> -CHROMA iFOB with <i>i</i> -CHROMA Reader	Predicate OC Auto Micro FOB Test with Polymedco OC Auto Micro 80Analyzer
Test Device	Test Cartridge (test strip enclosed in a plastic housing)	Sampling Bottle containing extraction buffer
Test Components	<i>i</i> -CHROMA iFOB Test Cartridge Sample Collection Tube containing the <i>i</i> -CHROMA iFOB Detection Buffer ID Chip which encodes the calibration data & <i>i</i> -CHROMA Reader <i>i</i> -CHROMA iFOB Negative and Positive Controls (sold separately)	Closed tube-type Sampling Bottle containing the Extraction Buffer. Test Reagents (Latex reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) & OC Auto Micro 80 Analyzer

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

FDA guidance “Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices” (Issue date: August 8, 2007)

FDA guidance “Format for Traditional and Abbreviated 510(k)s” (Issue date: August 12, 2005)

FDA guidance “Content of Premarket Submissions for Software Contained in Medical Devices” (Issue date: May 11, 2005)

Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)

CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition.

CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline – Second Edition.

CLSI, EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition, 05/21/2007.

CLSI, EP12-A2 User Protocol for Evaluation OF Qualitative Test Performance; Approved Guideline - Second Edition, Jan. 2008.

L. Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology. When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB). The test is performed using test cartridge, sample collection tube and ID chip of matching lot numbers. Test components of different lots are not interchangeable.

When the fecal sample mixture is loaded into the sample well on the test cartridge, it migrates through the nitrocellulose matrix of the test strip. The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip. As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody accumulate at the test line on test cartridge membrane. Thus, the more hemoglobin in the human fecal sample, the more complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line) as well as the control line.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which is proportional to intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample. The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer). The *i*-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The repeatability and reproducibility of *i*-CHROMA iFOB was evaluated by testing 20 replicates of fecal samples spiked with human blood to obtain test samples containing seven different concentrations of human hemoglobin: 50 ng/mL, 85 ng/mL, 90 ng/mL, 100 ng/mL, 110 ng/mL, 115 ng/mL and 1000 ng/mL.

Between site reproducibility study was conducted at three intended use sites in the US. Test samples were prepared at study site 1 and the same samples were tested at all the three US sites. The samples were shipped to the testing sites in Styrofoam boxes containing ice packs. *i*-CHROMA iFOB testing was carried out in a random and blinded manner. No invalid or indeterminate results were obtained throughout the precision studies.

Statistical analysis of repeatability and reproducibility studies of *i*-CHROMA iFOB

Type of Precision Study	Actual Results	Expected Results			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	<i>i</i> -CHROMA iFOB	Positive Results	Negative Results	Total Results			
Repeatability	Positive Results	77	00	77	97.86%	96.25% (89.55%~98.72%)	100.00% (93.98%~100.00%)
	Negative Results	03	60	63			
	Total Results	80	60	140			
Lot-to-Lot Reproducibility	Positive Results	234	01	235	98.33%	97.50% (94.65%~98.85%)	99.44% (96.92%~99.90%)
	Negative Results	06	179	185			
	Total Results	240	180	420			
Between-run Reproducibility	Positive Results	231	01	232	97.62%	96.25% (93.03%~98.02%)	99.44% (96.92%~99.90%)
	Negative Results	09	179	188			
	Total Results	240	180	420			
Between Instrument Reproducibility	Positive Results	234	01	235	98.33%	97.50% (94.65%~98.85%)	99.44% (96.92%~99.90%)
	Negative Results	06	179	185			
	Total Results	240	180	420			
Between-site Reproducibility	Positive Results	231	03	234	97.14%	96.25% (93.03%~98.02%)	98.33% (95.22%~99.43%)
	Negative Results	09	177	186			
	Total Results	240	180	420			
Combined Reproducibility	Positive Results	930	06	936	97.86%	96.88% (95.57%~97.80%)	99.17% (98.19%~99.62%)
	Negative Results	30	714	744			
	Total Results	960	720	1680			

b. Linearity/assay reportable range:

Control material was used as test samples for determining the measuring range of *i*-CHROMA iFOB. Two sets of control samples were tested: one set of 16 levels of human hemoglobin A₀ (5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 90, 100, 110, and 120 ng/mL) to cover the lower measuring range and the second set of 8 levels of human hemoglobin A₀ (800, 850, 900, 950, 1000, 1100, 1250, and 1500 ng/mL) to cover the higher measuring range. Nine replicates of test samples at each of the above analyte levels were tested in a single run by the same operator using same lot of test components and same instrument at the same testing site on the same day. Numerical values of test results of the nine replicates at each analyte level were statistically analyzed to calculate the mean, standard deviation and coefficient of variation (% CV). The lowest concentration of analyte showing coefficient of variation below 10% was considered as the lower limit of the measuring range. The highest concentration of analyte showing coefficient of variation below 10% was considered as the upper limit of the measuring range. The measuring/reportable range of *i*-CHROMA iFOB is 25.00–1000.00 ng/mL

(hemoglobin in the human fecal sample processed with *i*-CHROMA iFOB Detection Buffer).

Prozone (Hook Effect)

Susceptibility of *i*-CHROMA iFOB to prozone effect was evaluated by testing 20 replicates of hemoglobin-negative stool samples spiked with human blood (with known hemoglobin level) to obtain fecal samples containing 14 different hemoglobin concentrations 700 ng/mL up to 2000 ng/mL.

i-CHROMA iFOB was not found susceptible to prozone/hook effect as it would display positive test results with fecal samples containing hemoglobin concentration up to 2000 ng/mL.

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

i-CHROMA iFOB Test as well as the Controls are traceable to the IRMM/IFCC-467 Human Hemoglobin Reference Standard and OC-Standard V-IX50.

Internal Control: Procedural controls are included in the test device. The control line serves as an internal procedural control, indicating that the test system is functioning correctly and that the operator added a sufficient volume of sample.

External Quality Control: *i*-CHROMA iFOB Negative & Positive Controls are available in a separate control kit. The negative and positive controls are run in the iFOB Test in the same manner as an extracted fecal sample. It is recommended that positive and negative controls be performed to verify proper test performance.

Stability Studies

1. Stability of fecal samples

- a. Collected in *i*-CHROMA iFOB Sample Collection Tubes: Samples for stability testing were prepared by spiking stool samples with human blood (with known hemoglobin level) to obtain fecal samples containing six different hemoglobin concentrations: 50 ng/mL, 75 ng/mL, 90 ng/mL, 110 ng/mL, 125 ng/mL and 150 ng/mL. Each spiked sample was mixed with detection buffer in 10 *i*-CHROMA iFOB sample collection tubes. Six sets, each of 10 sample collection tubes (containing fecal samples spiked with the same level of hemoglobin) were individually enclosed in sample sacs, sealed in return envelopes and stored 4°C, 25°C, 37°C and 45°C for 120 hours/five days immediately after sampling. Each sample was tested with *i*-CHROMA iFOB initially (at 0 hour) and daily thereafter at time intervals: 24, 48, 72, 96 and 120 hours.
i-CHROMA iFOB 'Negative and Positive Controls' were also tested daily to ensure and confirm the validity of the test results of the stability study. Fecal samples submitted by the patient in *i*-CHROMA iFOB sample collection tube should be tested before 72 hours after sampling if stored at 4°C (2~8°C/35.6~46.4°F) and before 48 hours after sampling if stored at ambient temperature not exceeding 37°C/98.6°F.

b. Not collected in *i*-CHROMA iFOB Sample Collection Tubes: For fecal samples that are collected in a container other than the sample collection tubes provided with the *i*-CHROMA iFOB kit, the samples have to be transferred into the *i*-CHROMA iFOB Collection Tubes before testing. The following study was performed to determine the maximum allowable time after sampling for testing:
Samples for stability testing were prepared by spiking stool with human blood (with known hemoglobin level) to obtain fecal samples containing six different hemoglobin concentrations: 50 ng/mL, 75 ng/mL, 90 ng/mL, 110 ng/mL, 125 ng/mL and 150 ng/mL.
Separate specimen cups containing the spiked fecal samples were stored 4°C, 25°C, 37°C and 45°C for 120 hours/five days immediately after spiking/preparation.
Each test sample was tested with *i*-CHROMA iFOB initially (at 0 hour) and daily thereafter at time intervals: 24, 48, 72, 96 and 120 hours.
i-CHROMA iFOB ‘Negative and Positive Controls’ were also tested daily to ensure and confirm the validity of the test results of the stability study.
Fecal samples submitted by the patient in a specimen cup should be tested before 72 hours after sampling if stored at 4°C (2~8°C/35.6~46.4°F) and before 24 hours after sampling if stored at ambient temperature not exceeding 37°C/98.6°F.

2. *i*-CHROMA iFOB Controls Stability Study: Vials of three different lots of *i*-CHROMA iFOB ‘Negative’ and ‘Positive’ Controls were stored in sealed conditions at 2°C, 8°C and 25°C and used for stability testing over a period of 10 months. To demonstrate stability of the controls, *i*-CHROMA iFOB test cartridges (stored at 4~30°C) and *i*-CHROMA iFOB sample collection tubes (stored at 2~8°C in refrigerator) of matching lot number were used throughout the study period.
i-CHROMA iFOB controls from each lot stored at each of the three temperatures were tested initially at the start of the stability study (0 month) as well as every month (i.e. 29~31 days) thereafter over the period of 10 months.
For evaluating shelf-life stability, separate vials (of each lot) of the controls were used for each periodic testing. A vial once used for the initial or previous testing was not re-used for any successive periodic testing.
For evaluating open-vial stability, the same control vial was used for the initial as well as all successive periodic testing. Periodic/monthly *i*-CHROMA iFOB test results of the stored ‘Negative’ and ‘Positive’ controls were compared with the initial test results of corresponding vial/lot (i.e. at 0 month).
The *i*-CHROMA iFOB ‘Negative’ as well as ‘Positive’ Controls have a closed-vial stability of three months and open vial stability of one month under the recommended storage conditions of 2°C~8°C in a refrigerator.

d. *Detection limit*:

Control material was used as test samples for determining the limit of detection of *i*-CHROMA iFOB. Sixteen (16) levels of human hemoglobin A₀ (5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 90, 100, 110, and 120 ng/mL) were tested. Nine replicates of test samples at each of the above analyte levels were tested in a single run by the same operator using same lot of test components and same instrument at the same testing site on the same day. Numerical values of test results of the nine replicates at each analyte level were statistically analyzed to calculate the mean, standard deviation and coefficient of variation (% CV). The lowest concentration of analyte showing coefficient of variation below 10% was considered as the limit of detection. Accordingly the lower limit of detection was found to be 25 ng/mL (with 95% confidence interval 70.08~100).

e. Analytical specificity:

Sensitivity to human hemoglobin variant

Sensitivity of *i*-CHROMA iFOB to ‘Hemoglobin S’ as the human hemoglobin variant associated with sickle cell anemia was evaluated by testing 20 replicates of fecal samples spiked with blood of a sickle cell anemia patient to obtain test samples with five different concentrations of ‘Hemoglobin S’ (50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL). *i*-CHROMA iFOB was found to be equally sensitive to ‘Hemoglobin S’ as the human hemoglobin variant associated with sickle cell anemia.

Cross-Reactivity

Cross-reactivity of *i*-CHROMA iFOB with animal hemoglobin was evaluated by testing 20 replicates of hemoglobin-negative stool spiked with the intended level of respective animal hemoglobin such as bovine (2000 µg/mL), chicken (500 µg/mL), fish (100 µg/mL), horse/equine (500 µg/mL), goat (500 µg/mL), pig/swine (500 µg/mL), rabbit (500 µg/mL) and sheep (500 µg/mL). *i*-CHROMA iFOB did not show significant cross-reactivity with any of the animal hemoglobin tested.

Interfering Substances

Susceptibility of *i*-CHROMA iFOB to interference from endogenous substances was evaluated by testing 20 replicates of fecal samples spiked with human blood to obtain samples with 0 ng/mL, 50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL and 150 ng/mL concentrations of human hemoglobin and further spiking them with solutions containing intended concentrations of four endogenous substances: ascorbic acid (30 µg/mL), bilirubin (200 µg/mL), albumin (60 mg/mL) and myoglobin (2000 µg/mL). *i*-CHROMA iFOB did not show significant interference from any of the four endogenous substances tested.

f. Assay cut-off:

Analytical characterization of cut-off of the *i*-CHROMA iFOB involved testing of 219 human fecal samples comprising 125 normal/negative samples and 94 positive samples as confirmed with the predicate test OC Auto Micro FOB.

Test results were statistically analyzed by Receiver Operator Characteristics (ROC) Analysis and analyte concentration corresponding to maximum sensitivity as well as maximum specificity of *i*-CHROMA iFOB was taken as the cut-off.

Cut-off of *i*-CHROMA iFOB was determined to be 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer).

2. Comparison studies:

a. *Method comparison with predicate device:*

Due to administrative error, the following section in quotations was previously redacted:

“A clinical method comparison of *i*-CHROMA iFOB with the predicate test, OC Auto Micro FOB, was evaluated by testing fecal samples obtained from 134 patients (68 males and 66 females above the age of 50 years). Test samples were tested first with the ‘*i*-CHROMA iFOB’. The test samples were then tested with the comparator/predicate method ‘OC Auto Micro FOB’.”

A method comparison of *i*-CHROMA iFOB with the predicate test, OC Auto Micro FOB, was evaluated by testing spiked fecal samples at three intended use sites in the US. Test samples were prepared by spiking hemoglobin negative stool with human blood (with known hemoglobin level) to obtain fecal samples containing seven different hemoglobin concentrations: 50 ng/mL, 85 ng/mL, 90 ng/mL, 100 ng/mL, 110 ng/mL, 115 ng/mL and 1000 ng/mL. 20 aliquots of each spiked sample were tested with *i*-CHROMA iFOB at each testing site and then with the predicate test OC Auto Micro FOB. No invalid or indeterminate results were obtained throughout the analytical method comparison study. Statistical analysis of site-wise test results as well as combined results shows that *i*-CHROMA iFOB test results have acceptable overall percent agreement as well as positive percent agreement and negative percent agreement with OC Auto Micro FOB test results.

Statistical analysis of method comparison study of *i*-CHROMA iFOB

Study site	New Test	Predicate Test			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
	<i>i</i> -CHROMA iFOB	OC Auto Micro FOB					
		Positive Results	Negative Results	Total Results			
Study site 1	Positive Results	74	02	76	97.14%	97.37% (90.90% - 99.28%)	96.88% (89.30% - 99.14%)
	Negative Results	02	62	64			
	Total Results	76	64	140			
Study site 2	Positive Results	75	02	77	96.43%	96.15% (89.29% - 98.68%)	96.77% (88.98% - 99.11%)
	Negative Results	03	60	63			
	Total Results	78	62	140			
Study site 3	Positive Results	69	7	76	93.57%	97.18% (90.30% - 99.22%)	89.86% (80.51% - 95.00%)
	Negative Results	02	62	64			
	Total Results	71	69	140			
Combined sites	Positive Results	218	11	229	95.71%	96.89% (93.72% - 98.49%)	94.36% (90.18% - 96.82%)
	Negative Results	07	184	191			
	Total Results	225	195	420			

The above method comparison study demonstrated that the analytical performance of *i*-CHROMA iFOB test is substantially equivalent to the predicate device.

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):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected value is less than 8µg hemoglobin (Hb)/g of stool.

N. Instrument Name:

O. System Descriptions:

1. Modes of Operation:

Introduction of test strip cartridge

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ___ x ___ or No _____

3. Specimen Identification:

Enter Patient Identification Information manually on the label of *i*-CHROMA iFOB Sample Collection Tube.

e. Specimen Sampling and Handling:

It is recommended that the laboratory should give the *i*-CHROMA iFOB Sample Collection Tube to the patient so that the patient can collect fecal sample and do the sampling himself/herself and submit it to the laboratory for testing as per the appropriate instructions received from the laboratory.

The laboratory may also receive fecal samples which have been collected and submitted in specimen cups or similar containers by the patients. Such fecal samples may be stored at ambient temperature (up to 37°C) but must be processed (with detection buffer in the sample collection tube) and tested within 48 hours after collection. Fecal sample submitted by the patient in *i*-CHROMA iFOB sample collection tube should be tested before 72 hours after sampling if stored at 4°C (2~8°C/35.6~46.4°F) and before 48 hours after sampling if stored at ambient temperature not exceeding 37° C/98.6°F.

5. Calibration:

i-CHROMA iFOB ID chip (supplied in the test cartridge box) contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

6. Quality Control:

Internal Control: *i*-CHROMA iFOB test cartridge contains a 'control line' on which

'rabbit immunoglobulin-G antibodies' have been immobilized. The control line of *i*-CHROMA iFOB test cartridge functions as the built-in procedural control and indicate the following:

- a. A sufficient quantity of test sample (mixed with the detection buffer) was loaded into the sample well of the test cartridge.
- b. Test sample mixture loaded into the 'sample well' has migrated to the control line and test line of the test cartridge as required.
- c. All the components of *i*-CHROMA iFOB test functioned properly.
- d. Correct procedural technique for the *i*-CHROMA FOB test was followed.

External Controls: *i*-CHROMA iFOB Negative and Positive Controls. Both external controls are intended for monitoring and ensuring acceptable performance of the test system.

As *i*-CHROMA Reader is the associated instrument of *i*-CHROMA iFOB, the following electronic control mechanisms have been provided to check whether electronic features of the *i*-CHROMA Reader are within specifications:

- Pre-programmed 'System Self-Check' of *i*-CHROMA Reader
- System Check of *i*-CHROMA Reader using 'System Check Cartridge & ID Chip'

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

None

Q. Proposed Labeling:

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

R. Conclusion:

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