BIO TECHNOLOGY boditech

Tumor

ichroma™ iFOB

INTENDED USE

ichroma™ iFOB is a fluorescence Immunoassay (FIA) for the quantitative determination of hemoglobin in human feces. It is useful as an aid in management and monitoring of colorectal cancer.

For *in vitro* diagnostic use only.

INTRODUCTION

Colorectal cancer is the third most common cancer in the world[1], with about 1 million new cases and more than 500, 000 deaths per year. Screening method for colorectal cancer include the immuno chromatography fecal occult blood (iFOB) test, barium enema, sigmoidoscopy and colonoscopy[2]. Large randomized controlled trials have shown that iFOB screening can result in decreased colorectal cancer mortality[3,4]. The traditional FOB test uses the chemical Guaiac, which is sensitive to Hb peroxidase activity. However, the Guaiac-FOB test has low sensitivity to clinically significant colorectal neoplasis and has low specificity due to its non-specificity for human Hb[5,6]. To overcome these potential problems in immunochemical test, **ichroma™ iFOB** uses specific monoclonal antibodies against human Hb as capture and detection buffer.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by instrument for ichroma™ tests to show hemoglobin concentration in sample.

COMPONENTS

ichroma™ iFOB consists of 'Cartridges', an 'ID chip' and 'Sample Collection Tubes including a detection buffer'.

- The cartridge contains a test strip, the membrane which has anti human hemoglobin at the test line, while rabbit IgG at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human hemoglobin-fluorescence conjugate, anti rabbit IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is pre-dispensed in a sample collection tube. 25 sample collection tubes are packaged in a box and further packed in a styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Samples should not be taken during menstruation, hemorrhoids or when using rectal medications.
- There should be no contamination with urine or water in samples.
- Lot numbers of all the test components (Cartridge, ID chip and sample collection tube) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- Do not reuse. A sample collection tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- For shipping, samples must be packed in accordance with the regulations.
- Just before use, allow the cartridge, sample collection tube and sample to be at room temperature for approximately 30 minutes.
- **ichroma™ iFOB** as well as the instrument for ichroma™ tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for ichroma™ tests may produce minor vibration.
- Used sample collection tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **ichroma™ iFOB** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ iFOB** should be used only in conjunction with instrument for ichroma™ tests.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer pre-dispensed in a sample collection tube is stable for 20 months if stored at 2-8 °C.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF CFPC-15

Components of **ichroma™ iFOB**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Box containing Sample Collection Tubes
  - Sample Collection Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ iFOB**. Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
  - **ichroma™ D** REF 13303
- **ichroma™ Printer** REF FPRR007
- **Boditech iFOB Control** REF CFPO-105

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ iFOB** is human feces.

- Collect random samples of feces in a clean, dry container or a receptacle.
- Loosen a cap on the upper part of a sample collection tubes and remove a sampling stick. Use with care not to spill or splatter solution from the tube.
- Collect random samples by using a sampling stick with the proper method; insert the sampling stick and turn the stick into the fecal samples several times (5-6 times) at different sites so as to get a representative sampling.

※ Fill up the groove with fecal samples and please check whether the quantity is too much or not.

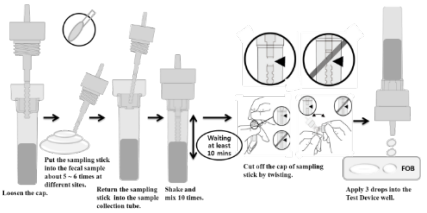
- Return the sampling stick into the Sample Collection Tube and screw the cap tightly.
- Shake the tube 10 times or more until the sample on the stick is dissolved.

★ Mixture can be kept for 3 days in a darkroom.

TEST SETUP

- Check the contents of **ichroma™ iFOB**: Sealed Cartridge, Sample collection Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the sample collection tube.
- Keep the sealed cartridge (if stored in refrigerator) and the sample collection tube at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for ichroma™ tests.
- Insert the ID Chip into the ID chip port of the instrument for ichroma™ tests**.**
- Press the 'Select' button on the instrument for ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE



1) Loosen and separate a sampling stick from a sample collection tube. (The socket between the stick and the tube should stay inside the tube).
2) Put a sampling stick into the fecal sample about 5 - 6 times at different sites and try to avoid obtaining clumps of fecal matter.
3) Return the fecal sampling stick into the sample collection tube. (Tighten the cap.)
4) Shake the tube 10 times or more until the sample on the stick is dissolved.
5) Mixture should be waiting at least 10 min. (It could be stored at darkness (4 - 28°C) for 3 days.)
6) Cut off the cap of sampling stick by twisting. (The tube must be vertical during this stick-cutting process.)
7) Load 3 drops of the mixture onto the sample well of the cartridge (refer to the picture above)
8) Leave the sample-loaded cartridge at room temperature for 10 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
9) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
10) Press 'Select' button on the instrument for ichroma™ tests to start the scanning process.
11) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
12) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays hemoglobin concentration of the test sample in terms of ng/mL.
- The cut-off (reference range): 50 ng/mL
- Working range : 25-1,000 ng/mL

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **ichroma™ iFOB**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance. (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

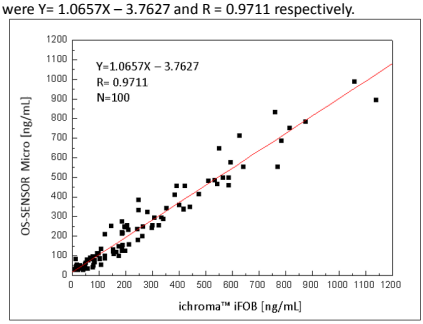
- **Specificity**: There, in test samples, are biomolecules such as bovine hemoglobin, swine hemoglobin, chicken hemoglobin were added to the test samples at concentrations much higher than their normal physiological levels in urine. **ichroma™ iFOB** test results did not show any significant cross-reactivity with these biomolecules.

- **Interference**: There, in test samples, are biomolecules such as ascorbic acid, bilirubin, albumin, glucose, lipids, barium sulfate were added to the test samples at concentrations much higher than their normal physiological levels in urine. **ichroma™ iFOB** test results did not show any significant interference with these biomolecules.

- **Precision**: The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **ichroma™ iFOB.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing three times each different concentrations.

Conc. [ng/mL]	Intra-assay			Inter-assay		
	Mean	S,D	CV (%)	Mean	S,D	CV (%)
25	25.52	0.37	1.46	25.4	0.41	1.62
50	50.64	0.81	1.61	50.72	1.59	3.13
75	76.11	1.26	1.65	75.55	2.06	2.73
100	101.68	1.75	1.73	101.54	4.03	3.97
250	254.58	5.66	2.22	252.34	8.93	3.54
500	509.02	11.2	2.2	507.73	18.56	3.66
750	754.37	17.21	2.28	752.09	27.18	3.61
1000	980.16	8.29	0.85	980.87	15.71	1.6

- **Comparability:** hemoglobin concentrations of 100 feces samples were quantified independently with **ichroma™ iFOB** and OC-SENSOR Micro as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 1.0657X – 3.7627 and R = 0.9711 respectively.



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Note: Please refer to the table below to identify various symbols

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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