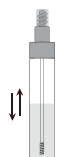
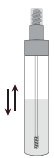
osom® iFOB Test

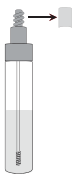


1. Shake the stool collection tube vigorously for 20 -30 seconds to ensure the sample is well mixed with the buffer. Some small amount of sample may not dissolve; this is normal.

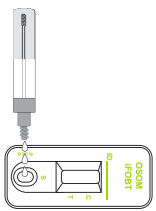
2. Remove test device from its foil pouch by tearing at the notch.



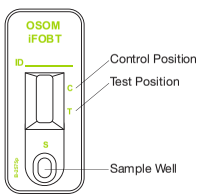
3. Tap the stool collection tube on a hard surface to dislodge any trapped air in top of cap. Invert tube several times to ensure all undissolved sample is dispersed in the buffer.



4. Unscrew tip cap on the stool collection tube.

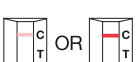


5. Holding the tube vertically above the sample well of the OSOM iFOB Test device, squeeze the tube gently to dispense three (3) drops into the sample well.

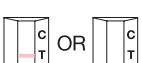


6. Read the result in 5-10 minutes.
Important: **DO NOT READ RESULTS AFTER 10 MINUTES.**

(examples of positive results)
Positive



(examples of negative results)
Negative



(examples of invalid results)
invalid

SEKISUI DIAGNOSTICS

Rev. P5576 04/15

OSOM® iFOB Test

CLIA Complexity: Waived

FOR LABORATORY AND PROFESSIONAL USE ONLY

IVD

INTENDED USE

OSOM iFOB Test 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. 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.

SUMMARY AND EXPLANATION

The American Cancer Society recommends that average-risk men and women over age 50 should be tested for fecal occult blood yearly or as often as their physician recommends[1]. Normally, a person may lose up to 1.5 mL of blood per day in the stool. Blood loss greater than 3 mL may be indicative of an abnormal condition. Patients with a family history of intestinal disorders or colorectal cancer, as well as those with personal histories of inflammatory bowel diseases such as polyps, colitis, and diverticulitis, should be monitored more frequently for occult blood in the stool[2,3]. Digital examination, proctosigmoidoscopy, or colonoscopy is also recommended. Polyps, the precursors of colorectal cancer, can be treated successfully if detected early.

OSOM iFOB Test (Fecal Occult Blood Test) is designed to detect fecal occult blood that can be caused by a number of conditions such as ulcers, hemorrhoids, polyps, colitis, diverticulitis, cancer and fissures. Since these disease conditions may not produce visible symptoms in their early stages, the test may act as an early warning signal. Patients testing positive with the test must be examined thoroughly with other medical procedures[2,3].

PRINCIPLE

OSOM iFOB Test employs solid-phase chromatographic immunoassay technology to qualitatively detect the presence of FOB in human feces. The sample is collected in a tube with extraction buffer. 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 into 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.

REAGENTS AND MATERIALS PROVIDED

- 25-OSOM iFOB Test device in a sealed foil pouch. Test devices contain a combination of monoclonal antibodies directed against the globin of human hemoglobin.
- 25-Stool collection tube, with sampler, containing extraction buffer solution (PBS). Warning: Do not swallow – if spilled, wash with plenty of water.
- 25-Collection paper
- 25-Mailing Envelope
- 1-Instructions for use
- 25-Patient instructions for use
- 25-Biohazard labeled bags with absorbent pads

NOTE: Two extra test devices have been included in the kit for external QC testing.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- External controls
- Latex gloves
- iFOB External Control Kit Sold Separately (Catalog # 1000)

STORAGE CONDITIONS
Store the kit or kit contents 2-30°C (36-86°F) until use. Do not freeze. The test device is stable until the expiration date printed on the pouch.

WARNING AND PRECAUTIONS
- For *in vitro* diagnostic use only.
- Read directions for use carefully before performing this test procedure.
- Treat fecal samples and used test materials as if they are potentially infectious.
- Do not reuse the test device.
- Do not use the test beyond the expiration date indicated on the pouch.

SPECIMEN COLLECTION AND TEST PROCEDURES
- To avoid false results, specimens should not be collected while the patient has bleeding hemorrhoids or constipation, cuts on hands, during menstrual period or immediately after menstrual period.
- Hands and test area should be kept clean and free from blood to avoid false positive results.
- The American Cancer Society recommends home collection of two samples from three consecutive specimens for a total of 6 samples.[4]

Sample Collection
1. Deposit the fecal sample on collection paper or in a clean container.

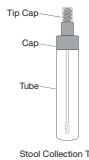
NOTE: Do not allow collection paper or feces to come into contact with toilet water or urine. The sample should not be tested if it becomes wet or contaminated. If this happens, place a clean tissue on the collection paper, then collect new feces sample for testing.

2. Unscrew the sampler from the stool collection tube with the fecal sample still on collection paper, randomly insert the grooved end of the sampler into the fecal sample in at least 6 different sites. Ensure the grooved end of the sampler is completely covered with fecal sample.

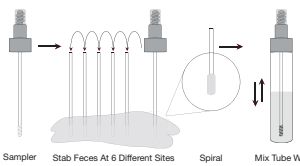
3. Insert the sampler into the stool collection tube and firmly tighten it. Do not reopen.

4. Shake the tube vigorously to mix the sample and the extraction buffer.

NOTE: The extracted fecal sample may be stored at room temperature for up to 10 days.



Stool Collection Tube

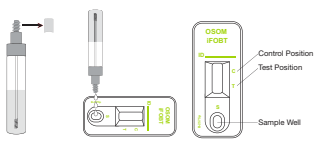


Sample Application and Result Reading
1. Shake the stool collection tube vigorously for 20-30 seconds to ensure the sample is well mixed with the buffer. Some small amount of sample may not dissolve; this is normal.

2. Remove test device from its foil pouch by tearing at the notch.

3. Tap the stool collection tube on a hard surface to dislodge any trapped air in top of cap.

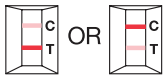
4. Invert tube several times to ensure all undissolved sample is dispersed in the buffer. Unscrew tip cap on the sample collection tube. Holding the tube vertically above the sample well of the OSOM iFOB Test device, squeeze the tube gently to dispense three (3) drops into the sample well.



5. Read the result in 5-10 minutes. Important: **DO NOT READ RESULTS AFTER 10 MINUTES**.

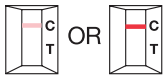
INTERPRETATION OF RESULTS

Positive
A reddish line appearing in the Control Position (C), and another reddish line in the Test Position (T), indicates that human hemoglobin has been detected in the sample. One line may be darker or lighter than the other, but even very faint reddish lines remain valid. Any positive result should be followed up with further examination to establish the source of bleeding.



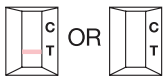
(examples of positive results)

Negative
Only one red line appearing in the Control Position (C), with NO reddish line in the Test Position (T), indicates that human hemoglobin has not been detected in the sample.



(examples of negative results)

Invalid
If no reddish line appears in the Control Position (C), the test result is invalid and the sample remaining in the stool collection Tube should be re-tested with a new test device.



(examples of invalid results)

QUALITY CONTROL

Internal Procedural Control
The OSOM iFOB Test device contains a built-in Control line that serves as an internal procedural control. The presence of the Control line indicates that: an adequate sample volume was used; the reagents migrated properly; and the control antibody reagents are working properly.

External Quality Control
Good laboratory practice recommends the use of external positive and negative controls to assure the test reagents are working properly and that the user has performed test correctly. If the controls do not perform as expected, review the instructions for use to see if the test was performed correctly; repeat the test or contact Sekisui Diagnostics Technical Assistance at 800-332-1042 before performing patient specimens. Contact your supplier or Sekisui Diagnostics Technical Assistance for information about purchasing controls.

LIMITATIONS

- Results are not conclusive evidence of the presence or absence of gastrointestinal bleeding caused by cancer or pathology.
- As with any immunochemical test, a positive OSOM iFOB Test result should not be considered a conclusive diagnosis for gastrointestinal bleeding or pathology. Immunochemical FOB testing has been shown to be valuable in preliminary screening, particularly of asymptomatic populations, or as an aid to diagnosis. The test is not intended to totally replace other diagnostic procedures such as colonoscopy, flexible sigmoidoscopy, or other imaging studies such as double contrast barium enema or CT colonography.
- Because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, a negative test result does not assure absence of lesions.
- A test result may be negative even when disease is present, because bowel lesions, including some colorectal cancers and significant polyps, may not bleed at all or may bleed intermittently, or the blood may not be uniformly distributed in a fecal specimen and therefore missed during sampling.
- Results may be positive for samples from patients without significant bowel pathology. Usually, the reasons for such false positive results are obscure, but in some cases, certain medications may cause gastrointestinal irritation resulting in occult bleeding.
- FOB testing is recommended annually by the American Cancer Society (2001) for average-risk women and men, 50 years of age and older. However, patients with significant risk factors such as family history of colorectal cancer should be screened earlier and more often.
- The intended use of OSOM iFOB Test for pediatric patients (21 years and below) has not been established.

PERFORMANCE CHARACTERISTICS

Sensitivity (Analytical Detection Limit)
Using dilutions of material with known hemoglobin concentration assayed by standard reference methodology, the analytical detection limit, or sensitivity, of OSOM iFOB Test has been set at 50 ng hHb/mL buffer or 50 µg hHb/g feces.

Method Comparison Study
The performance of OSOM iFOB 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 OSOM iFOB 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 OSOM iFOB Test agreed 100% with expected results and the results of the predicate.

Reproducibility Study
The performance of OSOM iFOB 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.

SPECIFICITY
OSOM iFOB Test is specific for human hemoglobin. Samples containing the following substances (per mL of buffer or g of feces), when spiked in both positive and negative samples, did not interfere with the test results.

Potentially Interfering Substance	Concentration Tested
Beef Hb	1 mg/mL
Pig Hb	1 mg/mL
Horse Hb	1 mg/mL
Rabbit Hb	1 mg/mL
Iron	1 mg/mL
Ascorbic Acid	5 mg/mL
Sheep blood	0.1 mL/g feces
Goat blood	0.1 mL/g feces
Chicken blood	0.1 mL/g feces
Beef meat extract (fresh/boiled)	1 mL/g feces
Chicken meat extract (fresh/boiled)	1 mL/g feces
Fish meat extract (fresh/boiled)	1 mL/g feces
Horse meat extract (fresh/boiled)	1 mL/g feces
Pork meat extract (fresh/boiled)	1 mL/g feces
Rabbit meat extract (fresh/boiled)	1 mL/g feces
Goat meat extract (fresh/boiled)	1 mL/g feces
Cauliflower extract (fresh/boiled)	1 mL/g feces
Broccoli extract (fresh/boiled)	1 mL/g feces
Parsnip extract (fresh/boiled)	1 mL/g feces
Cantaloupe extract (fresh/boiled)	1 mL/g feces
Red radish extract (fresh/boiled)	1 mL/g feces
Raw turnip extract (fresh/boiled)	1 mL/g feces
Toilet water	0.1 mL/g feces
Fluoride	0.1 mL/g feces

REFERENCES

1. American Cancer Society. Colorectal Cancer Screening Guidelines: http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_Can_colon_and_rectum_cancer_be_found_early.asp?sitearea=
2. Mitchell SH, Schaefer DC, Dubagunta S. Am Fam Physician. 2004 Feb 15;69(4):875-81.
3. Rockey DC. Occult gastrointestinal bleeding. N. Engl. J. Med. 1999;341:38-46.
4. Smith RA, von Eschenbach AC, Wender R, Levin B, Byers T, Rothberger D, Brooks D, et al. American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Adenomatous Polyps and Colorectal Cancer. CA-A Cancer J Clin. 2001; 51:44-54.

ASSISTANCE
For assistance call Sekisui Diagnostics Technical Assistance at (800) 332-1042 (U.S. only).

RE-ORDER
1002 25 Test Kit

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SYMBOLS KEY

	Instructions For Use (Read)
REF	Item Number
	Store At
	Expiration Date
CONT	Contents
DEV	Test Device
IFU	Instructions For Use
PRO	Procedure Card
ENV	Mailing Envelope
	Biohazard material
CT	Collection Tube
CP	Collection Paper
PI	Patient Instructions
	Do Not Reuse
IVD	For *In Vitro* Diagnostic Use
LOT	Lot Number
	Manufacturer
MF	Manufactured For