SCREEN®

SCREEN IFA TEST FOB (Feces) Package Insert

REF: SC-1361	English

A rapid test for the diagnosis of Human Occult Blood in feces with the use of SCREEN® Fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE

The FOB Test Cassette (Feces) is intended for in vitro quantitative detection of Human Occult Blood in feces.

SUMMARY

Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood (FOB), Human Occult Blood, or Human Hemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.1,2
The FOB Test Cassette (Feces) is a rapid test to quantitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 10-1000ng/ml. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The FOB Test Cassette (Feces) detects Human Occult Blood in feces based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains hemoglobin, it attaches to the fluorescent microspheres-conjugated anti-hemoglobin antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of hemoglobin in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of hemoglobin in the sample can be calculated by SCREEN® Analyzer.

REAGENTS

The test includes anti-hemoglobin antibody coated fluorophores and anti- hemoglobin antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The FOB Test Cassette should only be used with the Analyzer by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

1. Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
2. Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
3. No dietary restrictions are necessary before using the FOB Test Cassette.
4. Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present).Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.

MATERIALS

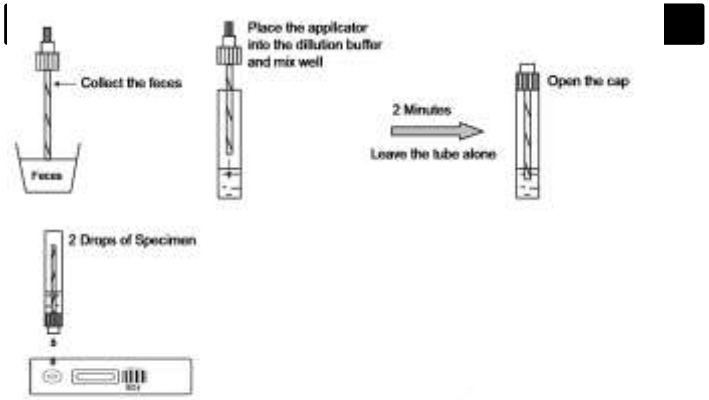
Materials Provided
• Test Cassettes • Specimen Collection Tubes with Buffer
• ID Card • Package Insert
Materials Required But Not Provided
• Timer • Centrifuge • SCREEN® Fluorescence Immunoassay Analyzer
• *Pipette* • *Specimen Collection Containers*

DIRECTION OF USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyzer power. Then according to the need, select “Standard Test” or “Quick Test” mode.
2. Take out the ID card and insert it into the Analyzer ID Card Slot.
3. To process fecal specimens:
   • For Solid Specimens:
   Unscrew the cap of the specimen collection tube，then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   • For Liquid Specimens:
   Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops (approximately 80 µL**) into the specimen collection tube containing the extraction buffer.
4. Tighten the cap onto the specimen collection tube, and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
5. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. To process fecal specimens.
6. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer **2 full drops of the extracted specimen (approximately 80 µL)** to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
7. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details

“Quick test” mode: After **15 minutes** of adding sample, Insert the test cassette into the Analyzer, click “**QUICK TEST**”, fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.

“Standard test” mode: Insert the test cassette into the Analyzer immediately after adding specimen, click “**STANDARD TEST**”, fill the test information and click **"NEW TEST"** at the same time, The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once.



Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for FOB is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer.
Linearity range of FOB Test is 10~1000 ng/mL.

QUALITY CONTROL

Each FOB Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an “N/A” message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The FOB Test Cassette (Feces) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of FOB.
2. The FOB Test Cassette (Feces) will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of FOB may produce a dose hook effect, resulting in incorrect interpretation of FOB levels. High dose hook effect has not been observed with this test up to 1000 ng/mL of FOB.
5. The results of FOB Rapid Tests are based on measuring the levels of FOB in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
< 50 ng/mL	Negative result
≥50 ng/mL	Positive result

PERFORMANCE CHARACTERISTICS

1.Accuracy
The test deviation is ≤±15%.
2. Sensitivity
The FOB Test Cassette (Feces) can detect levels of FOB as low as 10 ng/mL in feces.
3. Detection range
10~1000 ng/mL
4. Linearity range
10~1000 ng/mL , R≥0.990
5.Cross-reactivity
The FOB Test Cassette (Feces) is specific to human hemoglobin. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/ml, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

BIBLIOGRAFY

1. Simon JB. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, 1985; 88: 820.
2. Blebea J, Mcpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

	Consult Instructions For Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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