

Specimen: Feces  
Format: Cassette

### INTENDED USE

FOB Test Cassette is a qualitative test for detection of human occult blood in feces for self-testing.

### SUMMARY

Colorectal cancer is the third most common cancer in the world. "Fecal occult blood" is generally defined as a blood loss of less than 50 mL/d. The appearance of occult blood in human fecal specimen is often associated with gastrointestinal diseases which might cause colorectal cancer if not treated promptly and properly. The traditional guaiac-based method lacks sensitivity and specificity, and has diet restrictions prior to the testing.

FOB Test Cassette uses the technology of immunochromatographic sandwich assay. The test is more sensitive and more specific than the traditional guaiac assay. It is easier to interpret the result. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

### PRINCIPLE

FOB Test Cassette is composed of two units, a fecal collection tube and a test device. A fecal specimen is collected in the collection tube containing sample extraction buffer, and then added to the test device. When sample is added to sample pad, it moves through the conjugate pad and mobilizes the gold anti-human hemoglobin antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-human hemoglobin antibody that is coated on the test region. If human hemoglobin is present at levels of 50 ng/mL or greater, the result is the formation of a colored band in the test region. If there is no human hemoglobin in the sample, the area will remain colorless. The sample continues to move to the control area where goat anti-mouse IgG antibody will capture gold-antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

### REAGENTS AND MATERIALS PROVIDED

1. FOB Test Cassette device  
Test zone: contains mice monoclonal anti-human hemoglobin antibody.  
Control zone: contains goat anti-mouse IgG antibody.  
Conjugate pad: contains gold-mice monoclonal anti-human hemoglobin antibody conjugate.
2. Fecal specimen collection tube
3. The collection tube contains 2 ml of buffer, pH 7.6.
4. Instructions for use
5. Stool collection paper

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

### WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not open the foil pouch until you are ready to perform the test. If the test kit was stored refrigerated (2-8°C), bring the test components to room temperature before performing the test.
3. To guide the patients collect the samples according to

the insert. Do not collect the samples when the patients have hemorrhoids bleeding or during the menstrual period, which will lead to false positive results.

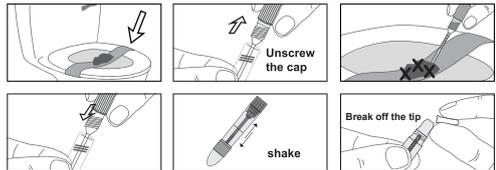
4. Interference substance in the samples or failed operation may cause false result. Please retest with a new one or use other way to confirm.
5. The test can not diagnose pathological changes in gastrointestinal tract bleeding, only for screening test. The test results can not instead of endoscopy, X-ray and other clinical analysis. For the positive result, please confirm the result by other clinical examination.
6. Patient specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedures.
7. The test device should not be reused.
8. Do not use kit beyond the expiration date.

### STORAGE

FOB Test Cassette should be stored at temperature 2-30°C in the sealed pouch for the duration of the shelf life (24months).  
Do the test in 1 hour when you open the pouch. **DO NOT FREEZE.**

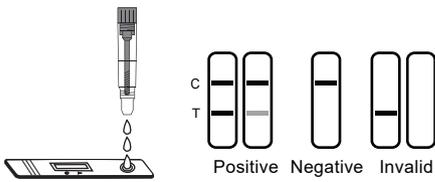
### SPECIMEN COLLECTION

1. The stool specimen should be collected in the stool collection paper or clean collection containers. Please use the stool collection paper, avoiding contamination of the specimen by taking precautions that the specimen or side of paper containing specimen does not come in contact with any contaminating objects including toilet cleaners.
2. Unscrew the top of the sample collection device, take out the sample collection stick, and collect the sample by dipping the stick into 3 different places of the stool sample.
3. Put the sample collection stick back in the sample collection device and screw together tightly.
4. If the sample cannot be tested on the day of collection, store the stool sample at 4°C. Bring the specimen to room temperature before testing.



### TEST PROCEDURE

1. Remove the test device from foil pouch by tearing along the notch.
2. Specimen collection. Please see also SPECIMEN COLLECTION
3. Shake the sample collection device several times.
4. Holding the sample collection device upright, carefully break off the top of collection device.
5. Squeeze 2-3 drops of the sample solution on the test sample well.
6. Read the results between 5 and 10 minutes.  
Note: Results read after 10 minutes may not be accurate.



## INTERPRETATION OF RESULTS

**Positive:** Two distinct pink-colored lines appear, one in the test region (T) and one in the control region (C).

**Negative:** Only one pink-colored line appears in the control region (C). No apparent pink line appears in the test region (T).

**Invalid:** Control Line fails to appear.

**NOTE:** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, please contact your local distributor.

## QUALITY CONTROL

FOB Test Cassette includes a procedural control in the test. If a FOB Test Cassette is valid and performed properly, a pink colored band will always appear in the C Region regardless positive or negative results.

It is recommended that negative and positive control specimens be used with each new kit. Users however, should follow their state or local regulations.

## PERFORMANCE CHARACTERISTICS

### Sensitivity:

The analytical sensitivity of the test is 50ng/mL human hemoglobin.

### Specificity:

FOB Test Cassette is specific to human hemoglobin. Samples containing the following substances were tested on both positive and negative controls with no effect on test results.

Substances	Concentrations
Pig hemoglobin	500µg/mL
Beef hemoglobin	500µg/mL
Goat hemoglobin	500µg/mL
Dog hemoglobin	500µg/mL
Chicken hemoglobin	500µg/mL
Rabbit hemoglobin	500µg/mL
Horseredish peroxidase	2mg/mL

### Diagnostic performance

Total 220 clinical samples include 80 FOB positive and 140 FOB negative, which were verified by certificated commercial kits and physician diagnoses, were tested with the test, the result was listed below:

Comparison test kit	FOB test kit		Total
	Positive	Negative	
Positive	79 (A)	1 (B)	80
Negative	2 (C)	138 (D)	140
Total	81 (A+C)	139 (B+D)	220

Diagnostic sensitivity=  $A/(A+B) \times 100\% = 79/80 = 98.75\%$

Diagnostic specificity=  $D/(C+D) \times 100\% = 138/140 = 98.57\%$

## LIMITATIONS OF THE PROCEDURE

1. 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.

2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## REFERENCE

- Simon J.B. "Occult blood screening for colorectal carcinoma: a critical review" ,Gastroenterology, Vol. 88 820, 1985.
- Woo. H. and McDonald C. "Detection of fecal occult blood using monoclonal antibodies" , Gasteroenterology society of Australia, Annual general Meeting. Melbourne, Victoria, Australia, May 1986.
- Adams, E.C. and Layman, K.M. "Immunochemical confirmation of gastrointestinal bleeding" , Ann. Elin. Lab. Sci., Vol. 4 343, (1974).
- Ribet, A., et al. "Occult-blood test and colorectal tumors", Lancet, Vol. 1, 417, (1980).
- Taranen, M.J., et al. "Immunological detection of fecal occult blood in colorectal cancer" , Br. J. Cancer, Vol. 49 141, (1984).

## INDEX OF SYMBOLS

	Do not re-use		Batch code
	In vitro diagnostic medical device		Use-by date
	Store at 2-30°C		Contains sufficient for <n>tests
	Authorized representative in the European Union		CE Mark
	Manufacturer		Consult instructions for use



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