

# Transferrin/FOB Combo Rapid Test Cassette (Feces)

## Package Insert

REF TTFC-625 English

A rapid, one step test for the qualitative detection of human hemoglobin and transferrin in human feces.

For professional in vitro diagnostic use only.

### INTENDED USE

The Transferrin/FOB Combo Rapid Test Cassette is a rapid chromatographic immunoassay (non-invasive assay) for the qualitative detection of human hemoglobin and transferrin in human feces specimens, which might be useful for the diagnosis of bleeding gastrointestinal disorders.

### SUMMARY

Colorectal cancer is cancer that occurs in the colon or rectum, and affects both men and women of all racial and ethnic groups, and is most often found in people aged 50 years or older. For men, colorectal cancer is the third most common cancer after prostate and lung cancers. For women, colorectal cancer is the third most common cancer after breast and lung cancers.

Fecal occult blood should be an important indicator in the diagnostic evaluation of patients with suspected gastrointestinal bleeding of any etiology, not just as an indication of colorectal cancer. The presence of human hemoglobin in feces is inadequate as a screening test for stomach cancer (upper gastrointestinal disorders), because of human hemoglobin derived from the upper digestive tract is broken down in the intestinal tract (the antigenicity is lost).

Detection of fecal transferrin, which is more stable in stool than hemoglobin, provides an alternative way of diagnosing the disease in the upper digestive tract.

Blood in the stool may be the only symptom of cancer, but not all blood in the stool is caused by cancer. Other conditions that can cause blood in the stool include: Haemorrhoids, Anal fissures, Colon polyps, Peptic ulcers, Ulcerative colitis, Gastroesophageal reflux disease (GERD), Crohn's disease, use of non-steroidal anti-inflammatory drugs (NSAIDs).

### PRINCIPLE

The Transferrin/FOB Combo Rapid Test Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of Human hemoglobin and transferrin in feces. The membrane is pre-coated with anti-hemoglobin antibody and anti-transferrin antibody on the test line region of the FOB and Transferrin. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody and/or anti-transferrin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody and/or anti-transferrin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test contains anti-hemoglobin antibody, anti-transferrin antibody particles and anti-hemoglobin antibody, anti-transferrin antibody coated on the membrane.

### PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

### STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

- 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.
- 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.
- No dietary restrictions are necessary before using the Transferrin/FOB Combo Rapid Test Cassette.

### MATERIALS

#### Materials Provided

- Test cassettes
- Specimen collection tubes with extraction buffer
- Package insert
- Specimen collection buffer

#### Materials Required But Not Provided

- Specimen collection containers
- Timer

### DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

#### 1. To collect fecal specimens:

Collect feces in a clean, dry specimen collection container. 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°C if not tested within 6 hours.

#### 2. To process fecal specimens:

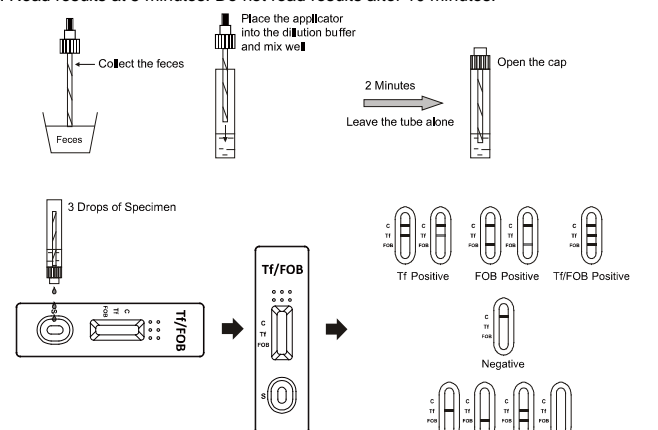
Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites. Do not scoop the fecal specimen.

Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C and 7 days at room temperature if not tested within 1 hour after preparation.

#### 3. 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.

Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 3 full drops of the extracted specimen (approximately 120µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.

#### 5. Read results at 5 minutes. Do not read results after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**Transferrin POSITIVE:**\* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the Transferrin line region (Transferrin).

**FOB POSITIVE:**\* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the FOB line region (FOB).

**FOB and Transferrin POSITIVE:**\* Three lines appear. One colored line should be in the control line region (C) and another two lines appear in the FOB and Tf regions.

**\*NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of human hemoglobin and/or human transferrin present in the specimen. Therefore, any shade of color in the FOB and/or Tf region should be considered positive.

**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the FOB and Tf region.

**INVALID:** Control line fails to appear. 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The Transferrin/FOB Combo Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
- The Transferrin/FOB Combo Rapid Test Cassette (Feces) will only indicate the presence of human hemoglobin and human transferrin, the presence of blood in feces does not necessarily indicate colorectal bleeding.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.

### EXPECTED VALUES

Common causes of Upper GI bleeding: duodenal ulcer (20-30%), gastric or duodenal erosions (20-30%), varices (15-20%), gastric ulcer (10-20%), erosive esophagitis (5-10%), angioma (5-10%), arteriovenous malformation (<5%), gastrointestinal stromal

tumours.

Common causes of Lower GI bleeding (percentages vary with the age group sampled): anal fissures, angiodysplasia (vascular ectasia), colitis (radiation, ischemic, infectious), colonic carcinoma, colonic polyps, diverticular disease, inflammatory bowel disease: ulcerative, proctitis/colitis, Crohn's disease, internal haemorrhoids

### PERFORMANCE CHARACTERISTICS

#### Accuracy

The Transferrin/FOB Combo Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test using clinical specimens.

#### FOB Results

Method	Other Rapid Test		Total Result	
	Results	Positive		Negative
Rapid Test Cassette for FOB	Positive	143	1	144
	Negative	3	289	292
Total Result		146	290	436

Relative sensitivity: 97.9% (95%CI\*: 94.1%~99.6%);

Relative specificity: 99.7% (95%CI\*: 98.1%~99.9%);

Accuracy: 99.1% (95%CI\*: 97.7%~99.2%). \*Confidence Intervals

#### Transferrin Results

Method	Other Rapid Test		Total Result	
	Results	Positive		Negative
Rapid Test Cassette for transferrin	Positive	91	2	93
	Negative	1	342	343
Total Result		92	344	436

Relative sensitivity: 98.9% (95%CI\*: 94.1%~99.9%);

Relative specificity: 99.4% (95%CI\*: 97.9%~99.9%);

Accuracy: 99.3% (95%CI\*: 98.0%~99.9%). \*Confidence Intervals

#### Sensitivity

The Transferrin/FOB Combo Rapid Test Cassette (Feces) can detect levels of Fecal Occult Blood as low as 50ng/ml and 40ng/ml human transferrin.

#### Precision

##### Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 50ng/ml, 100ng/ml and 10µg/ml FOB positive specimens. The specimens were correctly identified >99% of the time.

Within-run precision has been determined by using 15 replicates of three specimens: 40ng/ml, 80ng/ml and 1µg/ml Transferrin positive specimens. The specimens were correctly identified >99% of the time

##### Inter-Assay

Between-run precision has been determined by 15 independent assays on the same 6 specimens: 50ng/ml hemoglobin, 100ng/ml hemoglobin, 10µg/ml hemoglobin, 40ng/ml transferrin, 80ng/ml transferrin and 1µg/ml transferrin standard sample. Three different lots of the Transferrin/FOB Combo Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

#### Cross-reactivity

It was performed an evaluation to determine the cross reactivity and interferences of Transferrin/FOB Combo Rapid Test Cassette. There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces.

### BIBLIOGRAPHY

- WALKER C.W., "Fecal occult blood tests reduce colorectal cancer mortality.", Am Fam Physician. 2007 Jun 1;75(11):1652-3.
- CHIEN-HUA CHIANG, et al. «A comparative study of three fecal occult blood tests in upper gastrointestinal bleeding»; Kaohsiung J. Med. Sci May 2006, Vol 22, No 5: 223-228.
- HIROFUMI MIYOSHI, et al. «Accuracy of Detection of Colorectal Neoplasia using an Immunochemical Occult Blood Test in Symptomatic Referred Patients: Comparison of Retrospective and Prospective Studies. Internal Medicine Sept. 2000 Vol. 39, No. 9: 701-706

### Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged				

**Hangzhou AllTest Biotech Co., Ltd.**  
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