Chuangxingwell

CE

IVD

Fecal Occult Blood/Transferrin (FOB/TRF) Rapid Test Kit Package Insert

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

INTENDED USE

FOB/TRF Rapid Test Kit is a rapid chromatographic immunoassay (noninvasive assay) for the qualitative detection of human hemoglobin and transferrin in feces specimens. The results are useful for the diagnosis of bleeding gastrointestinal disorders.

SUMMARY AND EXPLANATION OF THE TEST

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 is 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 nonsteroidal anti-inflammatory drugs (NSAIDs).

BIOLOGICAL PRINCIPLE

The membrane of the Test Cassette is precoated with anti-hemoglobin antibody and anti-transferrin antibody on the test line regions for FOB and Transferrin. During testing, the specimen reacts with particles 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 colored lines. The presence of a colored line in either test line region indicates a positive result, while their 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/MATERIALS PROVIDED

The maximum number of tests obtained from this test kit is listed on the outer box.

- Test Cassettes: The test contains anti-hemoglobin antibody and anti-transferrin antibody-coated particles and anti-hemoglobin and anti-transferrin coated on the membrane.
- Specimen Collection Tubes with Extraction Buffer: a buffered solution containing Proclin 300 as a preservation. The Extraction Buffer is supplied in a dropper vial ready for use.
- Package insert

MATERIALS NOT PROVIDED

- Specimen collection containers
- Timer

PRECAUTIONS

1. For in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

SHELF LIFE AND STORAGE

The kit can be stored at room temperature or refrigerated (2-30 C) with a valid period of 24 months. 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. Use the test kit within 1 hour once the foil pouch is opened. DO NOT FREEZE. Do not use beyond the expiration date.

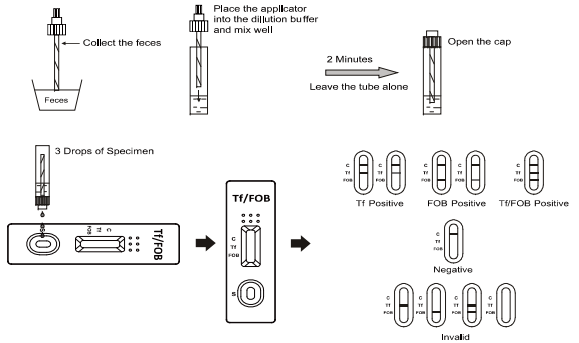
SPECIMEN COLLECTION AND PREPARATION

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 FOB/TRF Rapid Test Kit.

TEST PROCEDURE

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. Specimens 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 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.
4. 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 120 µL) 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 colored line should be in the Transferrin (TF) line region.

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 and Transferrin POSITIVE:* Three lines appear. One colored line should be in the control line region (C) and one line each at 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 or TF regions.

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

This test should be performed per applicable local, state, or federal regulations or accrediting agencies.

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.

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

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact your local distributor.

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.

LIMITATIONS OF THE PROCEDURE

1. FOB/TRF Rapid Test Kit is for in vitro diagnostic use only.
2. FOB/TRF Rapid Test Kit will only indicate the presence of human hemoglobin and human transferrin. The presence of blood in feces does not necessarily indicate colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

SPECIFIC PERFORMANCE CHARACTERISTICS

FOB/TRF Rapid Test Kit was compared with another leading commercial rapid test using clinical specimens.

FOB Results

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

Sensitivity: 97.9% (95% CI*: 94.1%~99.6%);
Specificity: 99.7% (95% CI*: 98.1%~99.9%);
Correlation: 99.1% (95% CI*: 97.7%~99.2%). *Confidence Intervals

Transferrin (TRF) Results

Method		Other Rapid Test		Total Result
Transferrin (TRF) Test Kit	Results	Positive	Negative	
	Positive	91	2	93
	Negative	1	342	343
Total Result		92	344	436

Sensitivity: 98.9% (95% CI*: 94.1%~99.9%);
Specificity: 99.4% (95% CI*: 97.9%~99.9%);
Correlation: 99.3% (95% CI*: 98.0%~99.9%). *Confidence Intervals

ANAYLTICAL SENSITIVITY

FOB/TRF Rapid Test Kit can detect concentrations of Fecal Occult Blood at 50 ng/mL or higher. It can detect human transferrin at 40 ng/mL or higher.

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision was determined using 15 replicates of seven specimens: negative, 50 ng/mL, 100 ng/mL and 10 µg/mL FOB positive specimens and 40 ng/mL, 80 ng/mL and 1 µg/mL Transferrin positive specimens. The specimens were correctly identified > 99% of the time.

Inter-Assay Precision

Between-run precision was determined by 15 independent assays on the same seven specimens: negative, 50 ng/mL hemoglobin, 100 ng/mL hemoglobin, 10 µg/mL hemoglobin, 40 ng/mL transferrin, 80 ng/mL transferrin and 1 µg/mL transferrin standard sample. Three different lots of FOB/TRF Rapid Test Kit have been tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

Various animal hemoglobins (Hbs) and transferrins (TFs) were spiked into diluting buffer at 1 mg/mL and tested with FOB/TRF Rapid Test Kit. None of the animal-derived proteins interfered including: Bovine Hb, Bovine TF, Chicken Hb, Chicken TF, Porcine Hb, Porcine TF, Goat Hb, Goat TF, Horse Hb, Horse TF, Rabbit Hb, Rabbit TF, Turkey Hb, Turkey TF.

TESTS FOR INTERFERING SUBSTANCES

FOB/TRF Rapid Test Kit was tested with various potentially interfering substances. None of the substances caused interference at the levels tested.

Ascorbic acid 20 mg/dL	Urea 2 g/dL
Oxalic acid 60 mg/dL	Glucose 2 g/dL
Bilirubin 100 mg/dL	Caffeine 40 mg/dL
Uric Acid 60 mg/dL	Albumin 2 g/dL
Acetosalicylic acid 20 mg/dL	

REFERENCES

1. Walker CW. Fecal occult blood tests reduce colorectal cancer mortality. Am Fam Physician. 2007 Jun 1;75(11):1652-3.
2. Chien-Hua C, et al. A comparative study of three fecal occult blood tests in upper gastrointestinal bleeding; Kaohsiung J Med Sci. 2006 May;22(5);223-228.
3. Hirofumi M, et al. Accuracy of detection of clorectal neoplasia using an Immunochemical occult blood test in symptomatic referred patients: Comparison of retrospective and prospective studies. Internal Medicine. 2000;39(9);701-706.

INDEX OF SYMBOLS

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
REF	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
EC REP	Authorized representative in the European Community		

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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