Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette (Feces)

Package Insert

REF TTFH-635 | English

A rapid, one step test for the qualitative detection of human hemoglobin, transferring and Haptoglobin/Hemoglobin complex in human feces specimen.
For professional in vitro diagnostic use only.

【INTENDED USE】
The Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay (non-invasive assay) for the qualitative detection of human hemoglobin, transferrin and Hemoglobin(Hb)-Haptoglobin(Hp) complex 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).
The Hemoglobin-Haptoglobin Complex Rapid Test immunological test based on the detection of the Hemoglobin-Haptoglobin (Hb-Hp) complex. Meguro, who also found excellent sensitivity and fecal extracts the Hb-Hp complex was more stable than unbound hemoglobin. Thus, in patients with proximal colorectal bleeding, the Hb-Hp complex could probably be detectable in stool, even after a longer passage.

【PRINCIPLE】
The Transferrin/FOB Combo Rapid Test Cassette (Feces)
The membrane is precoated 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.
The Hb-Hp Rapid Test Cassette (Feces)
The membrane is precoated with anti-haptoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-haptoglobin 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 and anti-haptoglobin antibodhy 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.

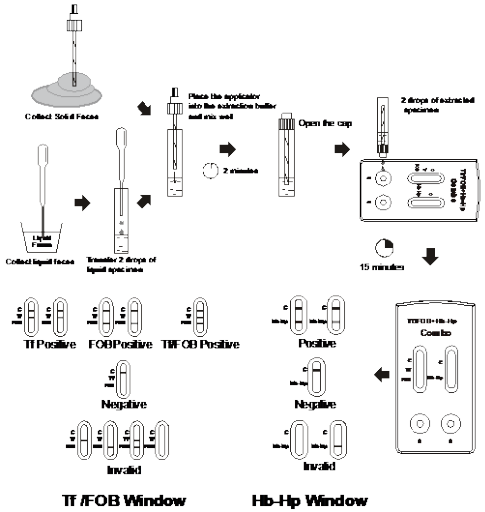
【STORAGE AND STABILITY】
The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【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 and Hb-Hp Combo Rapid Test Cassette.

【MATERIALS】
Materials Provided
• Test cassettes • Package insert
• Specimen collection tubes with extraction 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 sufficient quantity of feces (1-2ml or 1-2g) 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℃.
2. 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 80µL) into the specimen collection tube containing the extraction buffer.
3. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
4. 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.
5. 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.
6. Read results at 5 minutes after dispensing the specimen. Do not read results after 10 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 120µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



Tf /FOB Window **Hb-Hp Window**

【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 (Tf).
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.
Hb-Hp Complex Positive* Two line appear. One colored line should be in the control line region (C) and another apparent colored line should be in the Hemoglobin/Haptoglobin line region (Hb-Hp).
***NOTE**: The intensity of the color line in the FOB, Tf and Hb-Hp complex line region will vary depending on the concentration of human hemoglobin and/or human transferring and/or Hb-Hp complex present in the specimen. Therefore, any shade of color in the FOB and/or Tf and/or Hb-Hp region should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the FOB, Tf and Hp/Hb 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】
1. The Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
2. The Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette (Feces) will only indicate the presence of human hemoglobin, human transferring and human Hb-Hp complex in the feces specimen. 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.

【EXPECTED VALUES】
The Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test. The correlation between this two system is 99.1% for FOB, 99.3% for Tranferrin and 98.8% for Hb-Hp complex.

【PERFORMANCE CHARACTERISTICS】
Accuracy
The Transferrin/FOB and Hb-Hp 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
Rapid Test Cassette for FOB (Feces)	Results	Positive	Negative	
	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
Rapid Test Cassette for transferrin (Feces)	Results	Positive	Negative	
	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

Hp/Hb Complex Results

Method		Other Rapid Test		Total Result
Hb-Hp Complex Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	29	3	32
	Negative	1	297	298
Total Result		30	300	330

Relative sensitivity: 96.7% (95%CI*: 82.8%~99.9%);
Relative specificity: 99.0% (95%CI*: 97.1%~99.8%);
Accuracy: 98.8% (95%CI*: 96.9%~99.7%). *Confidence Intervals

Sensitivity
The Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette (Feces) can detect levels of 50ng/ml FOB, 40ng/ml Transferrin and 50ng/ml Hb-Hp complex.

Precision
Intra-Assay
Within-run precision has been determined by using 15 replicates of four specimens: negative, 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 four specimens: negative, 40ng/ml, 80ng/ml and 1µg/ml Transferrin positive specimens. The specimens were correctly identified >99% of the time.
Within-run precision has been determined by using 15 replicates of four specimens: negative, 50ng/ml, 200ng/ml and 2µg/ml Hb-Hp complex 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 4 specimens: negative, 50ng/ml hemoglobin, 100ng/ml hemoglobin, 10µg/ml hemoglobin, three different lots of Transferrin/FOB Combo Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.
Between-run precision has been determined by 15 independent assays on the same 4 specimens: negative, 40ng/ml transferrin, 80ng/ml transferrin, 1µg/ml transferrin, three different lots of Transferrin/FOB Combo Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.
Between-run precision has been determined by 15 independent assays on the same 4 specimens: negative, 50ng/ml Hb-Hp, 20ng/ml Hb-Hp, 2µg/ml Hb-Hp, three different lots of Hb-Hp Complex 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 and Hb-Hp Combo Rapid Test Cassette. There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces.

【BIBLIOGRAPHY】

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

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