One-Step Fecal Transferrin and Fecal Occult Blood (TRF-FOB) Combo Test Strip

Cat. No.：FOB 533

1. Intended use

One-Step Fecal Occult Blood and Transferrin (FOB-TRF) Combo Test strip is a rapid and convenient immunochromatographic assay for the qualitative detection of human hemoglobin and transferrin in human feces specimens. It is intended for professional use as an aid in the diagnosis of gastrointestinal bleeding caused by gastrointestinal diseases such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

2. Summary and principle of the assay

Fecal Transferrin (TRF) and Fecal Occult Blood (FOB) are both discharged in feces respectively following gastrointestinal bleeding. The presence of TRF and FOB in the feces indicates internal bleeding associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease.

One-Step TRF-FOB Combo Test strip is an antigen-capture immunochromatographic assay, detecting the presence of transferrin and/or fecal occult blood in fecal samples. Monoclonal antibodies specifically against human transferrin and hemoglobin, respectively, are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the Test Zone (T1 and T2) on the nitrocellulose membrane. When a fecal sample is added, it rehydrates the gold-antibody conjugate and the transferrin and / or hemoglobin, if any in samples, interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T1 and T2) where they are captured by immobilized antibodies, forming a visible pink line (indicate positive results). If transferrin and hemoglobin is absent in the sample, no pink line will appear in the Test Zone (T1 and T2), indicate negative results.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

3. Package contents

1) Pouch contents: FOB-TRF Test strip sealed with Desiccant.
2) Fecal Specimen Collection tube with sample buffer (2 ml/tube).
3) Test instructions.

4. Materials required (but not provided)

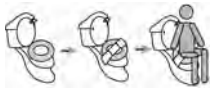
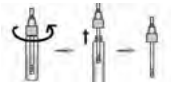
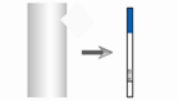
1) Glove.
2) Clock or timer.
3) 1.5 ml Eppendorf tube / vial.

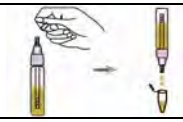
5. Warnings and precautions

1) For Professional *in vitro* diagnostic use only.
2) Do not reuse.
3) Do not use if the pouch seal or its packaging is compromised.
4) Do not use after the expiration date shown on the pouch.
5) Do not mix and interchange different specimens.
6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
7) Wash hands thoroughly after finishing the tests.
8) Do not eat, drink or smoke in the area where the specimens or kits are being handled.
9) Clean up spills thoroughly with appropriate disinfectants.
10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
11) Dispose of all specimens and used kits in a proper biohazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
12) Keep out of reach of children.

6. Procedure of the test

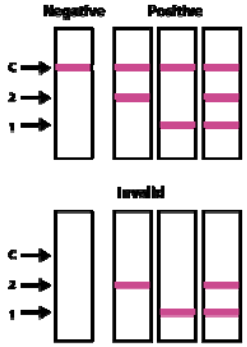
Allow test, specimen collection tube, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing and collect a random sample of feces in a clean, dry specimen collection container.

Place the sample collection pad on top of the toilet and deposit stool sample.	
Unscrew the cap of the fecal specimen collection tube and take out specimen collection stick.	
Stab the specimen collection stick into the fecal specimen in at least 3 different sites (Do not scoop the fecal specimen).	
Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	
Remove the FOB-TRF test strip from the sealed pouch and use it as soon as possible. Caution: Do not touch the membrane of the strip.	

Hold the fecal specimen collection tube upright and unscrew the tip with hands. Invert the vial and add eight full drops (400µl) of the specimen without air bubbles into a dry and clean 1.5 ml Eppendorf tube or vial.	
Immerse the FOB-TRF strip into the specimen with the arrow end pointing towards the specimen (Do not immerse past the MARK line). Take the strip out after a minimum of 10 seconds. Lay the strip (MARK side facing up) flat on a clean, dry, non-absorbent surface.	
Read the result within 15 minutes. NOTE: Specimens with high concentrations of TRF and/or FOB may produce positive results in as little as 1 minute. Confirm negatives in 15-30 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES	

Note: *Best results will be obtained if the assay is performed within 6 hours after collecting fecal samples. The collected specimen may be stored for 3 days at 2-8°C if not tested within 6 hours.*
Specimens prepared in the specimen collection tube may be stored for 3 days at 2-8 ℃ if not tested within 1 hour after preparation.

7. Interpretation of the test



Negative

A pink colored band appears only at the control region (C), indicating a negative result for TRF and FOB

Positive

A clear pink control band (C) and a detectable test band (2 and/or 1) appears, indicating a positive result:

2: TRF positive

1: FOB positive

Invalid

No visible band in the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

8. Result Reference

The reference below are given for orientation purpose only:

TRF	FOB	Digestive tract: Haemorrhage Level
+	+	Upper/lower, acute blood loss
+	-	Upper part, acute blood loss
-	+	Lower part, slight blood loss
-	-	No gastrointestinal bleeding

9. Performance data

1) Sensitivity is >99% compared to another commercial rapid test and the results of that guaiac assay.
2) Specificity is >99% compared to another commercial rapid test and the results of that guaiac assay.
3) Cross reactivity: there is not cross reactivity with common intestinal pathogens and substances occasionally present in feces: Rotavirus, Astrovirus, Campylobacter, Adenovirus, Escherichia coli, Giardia, Lactoferrin.

10. Quality Control

Although the testing strip contains an internal quality control (red colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

11. Storage and stability

1) Test device in the sealed pouches should be stored at 2-30ºC. Do not freeze the test device.
2) The fecal specimen collection device containing the buffer should be stored at 2-30ºC.
3) The test device should be kept away from direct sunlight, moisture and heat.

12. Limitations

1) This product is an in vitro diagnostic test designed for professional use only.
2) Humidity and temperature can adversely affect results.
3) The instructions for use of the test should be followed during testing procedures.
4) There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
5) Although the test demonstrates superior accuracy in detecting Helicobacter pylori antigen in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Manufacturer

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