

ALL TEST™ **FOB Rapid Test Cassette (Faeces)**
Package Insert
For Self-testing

REF TFO-602H English

A rapid one step test for the qualitative detection of Human Occult Blood in faeces.
 For self-testing in vitro diagnostic use only.

【INTENDED USE】

The FOB Rapid Test Cassette (Faeces) is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in faeces.

【SUMMARY】

Many diseases can cause hidden blood in the faeces. This is also known as Faecal Occult Blood (FOB), Human Occult Blood, or Human Haemoglobin. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.^{1,2}

The FOB Rapid Test Cassette (Faeces) is a rapid test to qualitatively detect low levels of Faecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Faecal Occult Blood at 50ng/ml or higher, or 6µg/g faeces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

【PRINCIPLE】

The FOB Rapid Test Cassette (Faeces) is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in faeces. The membrane is pre-coated with anti-haemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-haemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-haemoglobin antibody on the membrane and generate a coloured line. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured 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-haemoglobin antibody particles and anti-haemoglobin antibody coated on the membrane.

【PRECAUTIONS】

- For 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 haemorrhoids 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 FOB Rapid Test Cassette.

【MATERIALS】

Materials Provided

- Test Cassettes
- Package insert
- Specimen collection tubes with extraction buffer
- Stool catcher

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 faecal specimens:

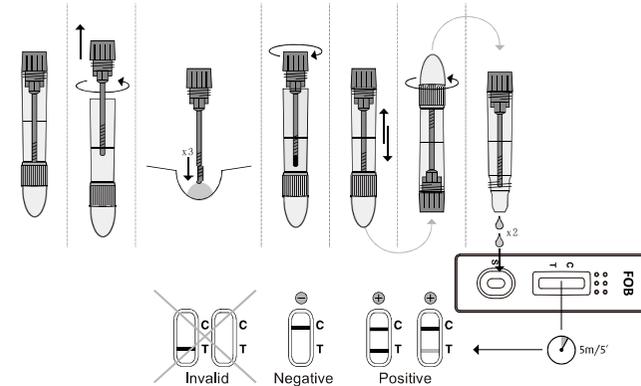
The stool specimen should be collected in the stool catcher. It is important to use the stool catcher to avoid contamination of the specimen with any kind of chemicals, so that no adulteration of the specimen occurs.

2. To process faecal specimens:

Unscrew the green cap of the specimen collection tube, then randomly stab the specimen collection applicator into the faecal specimen in at least 3 different sites. Do not scoop the faecal 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 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 as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and remove the clear cap. Turn the tube upside down and transfer 2 full drops of the extracted specimen (approximately 80µL) 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)

POSITIVE: * Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of Faecal Occult Blood present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).

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 coloured 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 FOB Rapid Test Cassette (Faeces) is for in vitro diagnostic use only.
2. The FOB Rapid Test Cassette (Faeces) will only indicate the presence of Faecal Occult Blood; the presence of blood in faeces 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.

【ADDITIONAL INFORMATION】

1. How does the test cassette work?

FOB Rapid Test Cassette detects human blood in faeces. The amount of blood increases as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures progresses.

2. How much occult blood can be detected in the faeces specimen?

The FOB Rapid Test could detect faecal occult blood at the level of 50ng/ml human haemoglobin or 6ug/g faeces.

3. How accurate is the test?

A clinical evaluation was conducted comparing the results obtained using the FOB Rapid Test to another commercially available FOB test. The consumer clinical trial included 464 faeces specimens; both assays correctly identified 63 positive and 397 negative results. The results demonstrated 99.1% overall accuracy of the FOB Rapid Test when compared to the other FOB rapid test.

4. How should the faeces specimen be stored?

Generally speaking, the fresh specimen should be used within 1 day at room temperature in order to get a correct result. If storing the specimen for longer than this, the sample must be frozen.

5. What should I do if the result is positive?

You should visit your doctor for advice.

Index of Symbols

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|--|-------------------------------------|--|---------------|--|---------------------------|
| | 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 | | | | |

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