Bowel Health Test

FOB Rapid Test (Faeces)

CE 0123 REF TFO-601H ENGLISH

INTENDED USE

A rapid test for the qualitative detection of human occult blood in faeces to aid in the diagnosis of bowel cancer. For self-testing *in vitro* diagnostic use only.

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 bowel cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, aside from occult blood. Traditional guaiac-based methods lack sensitivity and specificity, and also have diet restrictions prior to testing.[1,2]
The Bowel Health Test (FOB rapid test) is a rapid test to qualitatively detect levels of faecal occult blood. The test uses a double antibody sandwich assay to selectively detect faecal occult blood at 50 ng/mL or higher, or 6 µg/g faeces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The membrane of the Bowel Health Test (FOB rapid test) is pre-coated with anti-haemoglobin antibodies on the test line region (T) of the test. During testing, the specimen reacts with the particle coated with anti-haemoglobin antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-haemoglobin antibodies on the membrane and generate a coloured line. The presence of this coloured line in the test line region indicates a positive result (indicating the presence of faecal occult blood), while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region (C), indicating that the required volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-haemoglobin antibody particles and anti-haemoglobin antibodies coated on the membrane.

PRECAUTIONS

- For self-testing *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.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Keep out of the reach of children.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The dipstick test is stable until the expiration date printed on the sealed pouch. The dipstick test must remain in the sealed pouch until use.
Do not freeze. Do not use after 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 Bowel Health Test (FOB rapid test).

MATERIALS

Materials Provided

- Dipstick test
- Specimen collection tube with extraction buffer
- Reaction tube
- Stool catcher
- Instructions for use
- Product summary

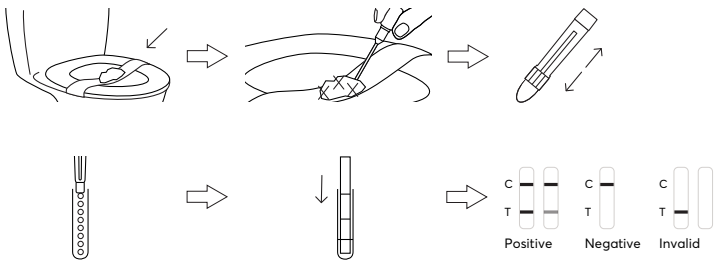
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.
To collect faecal specimens:

1. Secure the collection paper to the toilet using the adhesive tabs. Collect the faeces sample in the collection paper.
2. Unscrew the cap of the specimen collector tube, then insert the blue applicator into the faeces in at least 3 different places. You only need a small sample, about the size of a grain of rice. Screw the applicator back on tightly, then shake the tube to mix the specimen and the extraction buffer.
3. You can now flush the faeces and collection paper down the toilet - the paper is biodegradable.
4. Remove the test from the foil pouch and use it as soon as possible.
5. Unscrew the lid of the extraction buffer, break off the tip of the dropper then transfer 8-10 full drops of the extracted specimen to the reaction tube. Then with arrows pointing towards the extraction buffer, immerse the dipstick. Take care not to submerge beyond the maximum line. Start a timer.
6. Read the results after 5 minutes. Do not read after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
POSITIVE:* Two coloured 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). This indicates the presence of fecal occult blood in the stool.

*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). This indicates that faecal occult blood was not detected in the stool.

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.

LIMITATIONS

1. The Bowel Health Test (FOB rapid test) is for *in vitro* diagnostic use only.
2. The Bowel Health Test (FOB rapid test) 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.

FAQs

1. **How does the test dipstick work?**
The Bowel Health Test (FOB rapid test) detects human blood in faeces. The rate of disease progression is not indicated by this test.
2. **How much occult blood could be detected in the faecal specimen?**
The Bowel Health Test (FOB rapid test) can detect faecal occult blood at the level of 50 ng/mL or 6 µg/g faeces.
3. **How accurate is the test?**
A clinical evaluation was conducted comparing the results obtained using the Bowel Health Test (FOB rapid test) to another commercially available FOB test. The consumer clinical trial included 464 faecal specimens: The Bowel Health Test (FOB rapid test) identified 63 positive and 397 negative results. The results demonstrated 99.1% overall accuracy of the Bowel Health Test (FOB rapid test) when compared to the other FOB rapid test.
4. **How should the faecal specimen be stored?**
It is recommended to test the specimen as soon as possible after collection.
5. **What should I do if the result is positive?**
You should visit your doctor for advice.

BIBLIOGRAPHY

1. Simon JB. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, 1985; 88: 820.
2. Blebea J, Mcpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med,1985;109:437-40.

Index of Symbols

⚠	Caution	Σ	Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Manufacturer
	Non-recyclable	21	Pap 21 recyclable material	22	Pap 22 recyclable material

CE 0123

EC REP

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