Bowel Health Test

Self-test • FOB rapid test • dipstick • faeces

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 Bowel Health Test (FOB rapid test) 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 fecal 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, but only 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 low levels of fecal occult blood. The test uses a double antibody sandwich assay to selectively detect fecal 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 Bowel Health Test (FOB rapid test) is a qualitative, lateral flow immunoassay for the detection of human occult blood in faeces. The membrane is pre-coated with anti-haemoglobin antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-haemoglobin antibodies. The mixture migrates upward on the membrane chromatographically 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, 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 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.

[STORAGE AND STABILITY]
The kit can be stored at room temperature or refrigerated (2-30°C). The dipstick test is stable through 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 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 the Bowel Health Test (FOB rapid test).

[MATERIALS]

Materials Provided

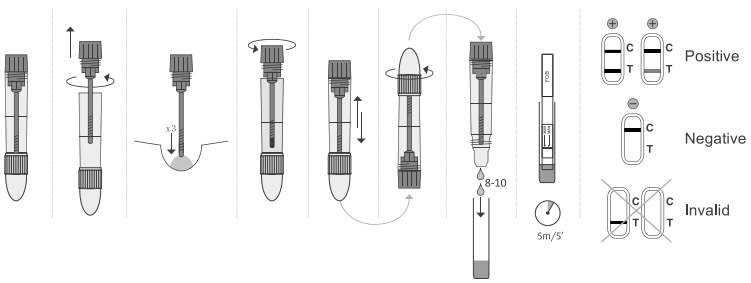
• Dipstick test
• Specimen collection tube with extraction buffer
• Reaction tube
• Stool catcher
• Package insert

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 fecal specimens:

1. The stool specimen should be collected in the stool catcher. It is important to use the stool catcher in all sorts of toilets to avoid contamination of the specimen with any kind of chemicals, so that no adulterations of the specimen occur.
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 specimen collection tube vigorously to mix the specimen and the extraction buffer.
3. Bring the pouch to room temperature before opening it. Remove the test 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. Fix te reaction tube, hold the specimen collection tube upright and break off the tip of the specimen collection tube. Invert the specimen collection tube and transfer 8-10 full drops of the extracted specimen (approx. 500µL) to the reaction tube, then with arrows pointing toward the extraction buffer, immerse the dipstick and start the timer. Do not immerse the dipstick past the maximum line. 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 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).
*NOTE: The intensity of the colour in the test line region (T) will vary depending on the concentration of fecal 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.

[LIMITATIONS]
The Bowel Health Test (FOB rapid test) is for *in vitro* diagnostic use only.
The Bowel Health Test (FOB rapid test) will only indicate the presence of fecal occult blood, the presence of blood in faeces does not necessarily indicate colorrectal bleeding.
As with all diagnostic tests, all results must be considered with other clinical information available to the physician. Other clinically available tests are required if questionable results are obtained.

[ADDITIONAL INFORMATIONS]
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 fecal specimen?
The Bowel Health Test (FOB rapid test) can detect fecal occult blood at the level of 50ng/ml or 6ug/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 fecal 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 fecal specimen be stored?
Generally speaking, the fresh specimen should be used within 1 day at room temperature, in order to get correct results.
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 Colorrectal 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

	Consult instructions for use		Tests per kit	EC REP	Authorised Representative
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

CE 0123

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