FOB Test
010L210-20

A rapid test for the qualitative detection of Human Occult Blood in feces.
For professional in vitro diagnostic use only

INTENDED USE
The ulti med FOB Test is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces.

SUMMARY
Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood (FOB), Human Occult Blood, or Human Hemoglobin. 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 ulti med FOB 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 40ng/ml or higher, or 4.8µg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

TEST PRINCIPLE
The ulti med FOB Test is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in feces. The membrane is precoated with anti-hemoglobin 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-hemoglobin 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-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

PRECAUTIONS
- For professional in vitro diagnostic use only.
- The test device should remain in the sealed pouch until use.
- Do not use the test if the foil pouch is damaged.
- Do not use after the expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- The used test should be discarded according to local regulations.
- Read the entire procedure carefully prior testing.
- Do not reuse tests.
- Humidity and temperature can adversely affect results.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

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. The kit should be kept out of direct sunlight.

- **Do not freeze**
- **Do not use beyond the expiration date.**

MATERIALS PROVIDED
- 20 Test cassettes
- 20 Clipbags with content:
  - 1 stool collection tube (content 2ml)
  - 1 stool sample collection unit
  - 1 short instruction for stool sample collection
- 1 Package insert

MATERIALS REQUIRED, BUT NOT PROVIDED
- Timer

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 ulti med FOB Test.

DIRECTIONS FOR USE
- **To collect fecal specimens:**
  - The stool specimen should be collected in the stool catcher. Please use the stool catcher in all sorts of toilets to avoid contamination of the specimen with any kind of chemicals, so that no adulteration of the specimen occur.
- **To process fecal specimens:**
  - Unscrew the white 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 white 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 and 7 days at room temperature if not tested within 1 hour after preparation.

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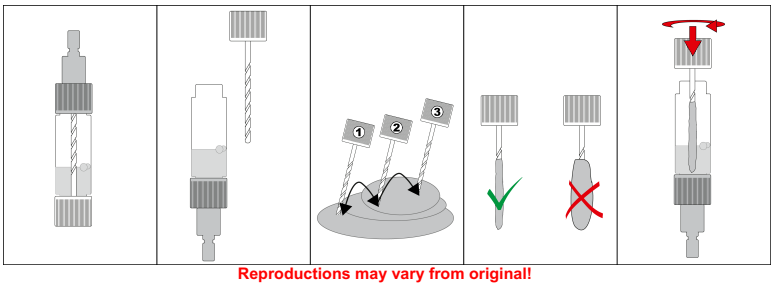
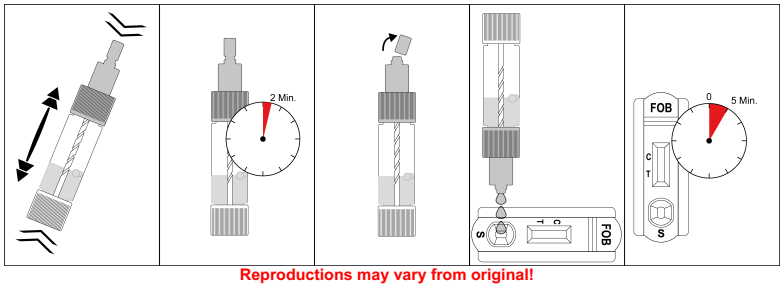


Reproductions may vary from original!

- **Test procedure:**
  - **Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**
  - 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.
  - Place the cassette on a clean and level surface.
  - Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Wait two minutes.
  - Hold the specimen collection tube upright and open the blue cap onto the specimen collection tube. **Leave the white cap tightly closed!**
  - Invert the specimen collection tube and transfer 3 full drops of the extracted specimen to the specimen well (S) of the test cassette, then start the timer. **Avoid trapping air bubbles in the specimen well (S).**
  - Read results at 5 minutes. Do not read results after 10 minutes.



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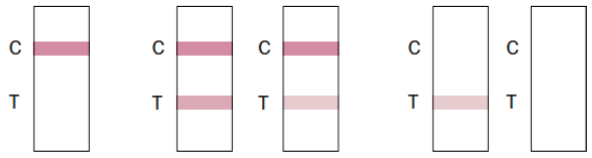
INTERPRETATION OF RESULTS



Negative: One coloured line appears in the control line region (C). No line appears in the test line region (T).
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).
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 using a new test device. If the problem persists, discontinue using the lot immediately and contact distributor / manufacturer.

*** 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.

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

- The ulti med FOB Test is for in vitro diagnostic use only.
- The ulti med FOB Test will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal 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.

EXPECTED VALUES

The ulti med FOB Test has been compared with another leading commercial rapid test. The correlation between these two systems is 98.9%.

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PERFORMANCE CHARACTERISTICS

Accuracy
The ulti med FOB Test has been compared with another leading commercial rapid test using clinical specimens.

Method		Other FOB Rapid Test		Total Results
ulti med FOB Test	Results	Positive	Negative	
	Positive	205	6	211
	Negative	5	800	805
Total Results		210	806	1016

Relative sensitivity: 97.6% (95%CI*: 94.5%~99.2%);
Relative specificity: 99.3% (95%CI*: 98.4%~99.7%);
Accuracy: 98.9% (95%CI*: 98.1%~99.5%).
*Confidence Intervals

Sensitivity
The ulti med FOB Test can detect levels of Fecal Occult Blood as low as 40ng/ml or 4.8 µg/g feces.

Precision
Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens: 40ng/ml, 200ng/ml and 10µg/ml 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 three specimens: 40ng/ml, 200ng/ml and 10µg/ml positive specimens. Three different lots of the ulti med FOB Test have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity
The ulti med FOB Test is specific to human hemoglobin. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/ml, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Goat hemoglobin, Horse hemoglobin, Pork hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

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.

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Expiration date
	Read instructions for use		Store at
	Keep away from direct sunlight	REF	Ordering number
	Keep dry		

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

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