

FOB Rapid Test Cassette (Feces)

Package Insert For Self-testing

A rapid one step test for the qualitative detection of Human Occult Blood in Feces.

For self-testing in vitro diagnostic use only.

【INTENDED USE】

The FOB Rapid Test Cassette (Feces) 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, but 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 (Feces) 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 50ng/ml or higher, or 6µg/g Feces. 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 (Feces) is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in Feces. The membrane is pre-coated 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 colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored 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 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 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 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 FOB Rapid Test Cassette.

【MATERIALS】

Materials Provided

- Test Cassette
- Specimen Collection Tube with Extraction Buffer
- Package Insert
- Stool Catcher

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:

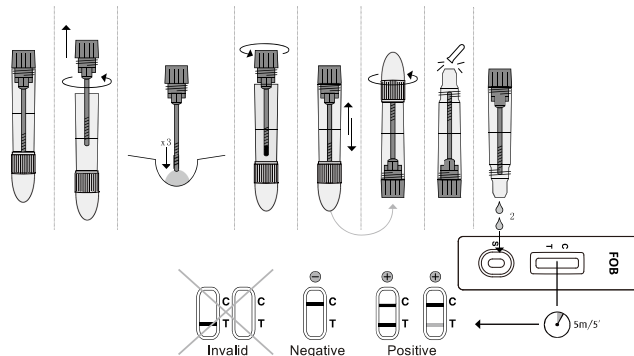
The stool specimen should be collected in the stool catcher. It is important to use the stool catcher in all sorts of toilets to avoid contamination of the specimen with any kind of chemicals, so that no adulteration of the specimen occurs.

- 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. Leave the tube to stand for 2 minutes.

- 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.
- Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Break off the tip. Invert the specimen collection tube 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.
- Read results at **5 minutes**. Do not read results after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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

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

NEGATIVE: One colored 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 colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

【LIMITATIONS】

- The FOB Rapid Test Cassette (Feces) is for *in vitro* diagnostic use only.
- The FOB Rapid Test Cassette (Feces) 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.

【ADDITIONAL INFORMATION】

1. How does test cassette work?

FOB Rapid Test Cassette detects human blood in feces. The rate of disease progression is not indicated by this test.

2. How much occult blood could be detected out in the Feces specimen?

The FOB Rapid Test can detect fecal occult blood at the level of 50ng/ml or 6ug/g Feces.

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 fecal specimens: The FOB test 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 feces 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】

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

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