

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 Dipstick (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, 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 Dipstick (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 Dipstick (Feces) 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 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 dipstick is stable through the expiration date printed on the sealed pouch. The test dipstick 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 Dipstick

【MATERIALS】
Materials Provided

- Test dipsticks
- Specimen collection tubes with extraction buffer
- Package insert
- Reaction Tubes
- Stool catcher

Materials Required But Not Provided

- Timer

【DIRECTIONS FOR USE】

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

1. 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.

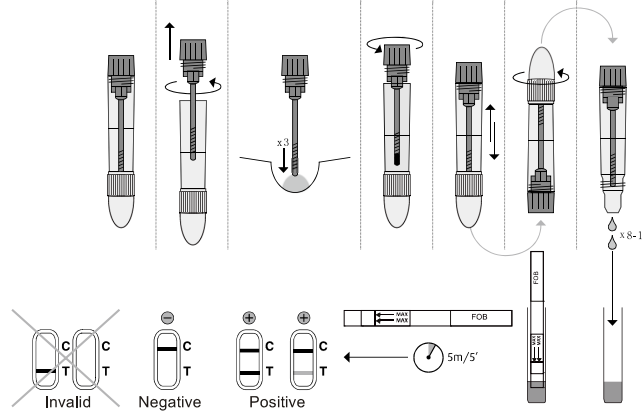
2. To process fecal specimens:

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. 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 dipstick 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 the 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 exaction 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 lines appear. One colored line should be in the control line region (C) and another apparent 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.

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 Dipstick (Feces) is for in vitro diagnostic use only.
2. The FOB Rapid Test Dipstick (Feces) will only indicate the presence of Fecal Occult Blood, the presence of blood in feces 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.

【EXPECTED VALUES】
1. How does the test dipstick work?

FOB Rapid Test Dipstick detects human hemoglobin in your feces specimen that your body produces during. The amount of hemoglobin increases as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures progresses was not confirmed

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

The FOB Rapid Test could detect fecal occult blood at the level of 50ng/ml human hemoglobin 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 feces specimens: both assays 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. What's the storage condition of the feces specimen

General speaking, the fresh specimen should be using out within 1 day at room temperature, in order to get a correct results, the best storage condition is freezing.

5. What should I do if the result shows occult blood in the fecal?

You should ask for a doctor according to the clinical symptoms, Anorectal mirror detection method is gold method to make sure gastrointestinal bleeding.

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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