

ROJAN® FOB

One Step Fecal Occult Blood Test Device (Feces) Package Insert

REF R-2303 English

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

INTENDED USE

The FOB One Step Fecal Occult Blood Test Device (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 One Step Fecal Occult Blood Test Device (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 50 ng/mL or higher, or 6 µg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The FOB One Step Fecal Occult Blood Test Device (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 device contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

PRECAUTIONS

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

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 One Step Fecal Occult Blood Test Device (Feces).

MATERIALS

Materials Provided

- Test devices
- Specimen collection tubes with extraction buffer
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test device, specimen collection tube, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- To collect fecal specimens:

Collect feces in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours.

- To process fecal specimens:

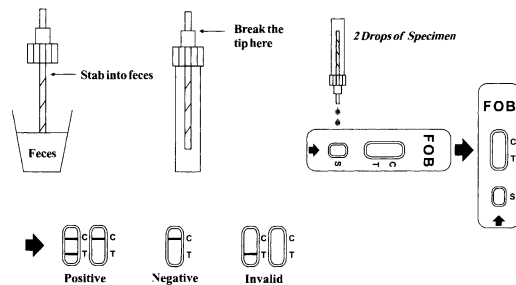
Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection stick into the fecal specimen in at least 3 different sites. Do not scoop the fecal specimen.

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.

- Remove the test device from the sealed pouch and use it as soon as possible.

- Hold the specimen collection tube upright and break off the tip of the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approx. 90 µL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.

- Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

NEGATIVE: One colored line appears in the control line region (C). No apparent colored 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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 FOB One Step Fecal Occult Blood Test Device (Feces) is for *in vitro* diagnostic use only.
- The FOB One Step Fecal Occult Blood Test Device (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.

EXPECTED VALUES

The FOB One Step Fecal Occult Blood Test Device (Feces) has been compared with another leading commercial rapid test. The correlation between these two systems is 98%.

PERFORMANCE CHARACTERISTICS

Accuracy

The FOB One Step Fecal Occult Blood Test Device (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method	Other Rapid Test		Total Results	
	Results	Positive		Negative
	FOB One Step Test Device	Positive		206
	Negative	14	847	861
	Total Results	220	855	1075

Relative Sensitivity: 96.3% (89.6% - 96.5%) Relative Specificity: 99.1% (98.2% - 99.6%)
Relative Accuracy: 98.0% (96.9% - 98.7%) * 95% Confidence Intervals

Sensitivity

The FOB One Step Fecal Occult Blood Test Device (Feces) can detect levels of Fecal Occult Blood as low as 50 ng/mL or 6 µg/g feces.

Specificity

The FOB One Step Fecal Occult Blood Test Device (Feces) 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, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

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.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		

ISO, GMP

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