

Fecal Occult Blood Rapid Test Cassette (Feces)
Package Insert

REF L031-30121 English

A rapid test for the qualitative detection of human occult blood in feces
For professional *in vitro* diagnostic use only

INTENDED USE

The Fecal Occult Blood 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. 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. The traditional guaiac-based method lacks sensitivity and specificity, and has diet-restrictions prior to testing.

The Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses a double antibody sandwich assay to selectively detect fecal occult blood at 50 ng/mL or higher, or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

The Fecal Occult Blood 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 Cassette. 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 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 Cassette 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.
- 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 the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

Patient 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.
- Dietary restrictions are not necessary.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch.
- DO NOT FREEZE.**

SPECIMEN COLLECTION PREPARATION

- The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.

MATERIALS

Materials Provided

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

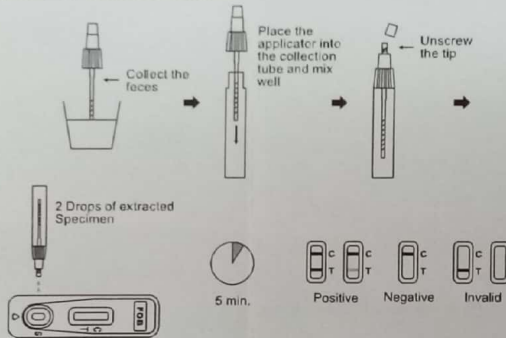
Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

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

- To collect fecal specimen: Collect feces in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimens collected may be stored for 3 days at 2-8°C if not tested within 6 hours.
- To prepare fecal specimen:
 - 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 to collect feces and transfer to the specimen collection tube. Do not scoop the fecal specimen.
 - Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
- Remove the test Cassette from the sealed pouch and use it as soon as possible.
- Place the test Cassette on a clean and level surface. Hold the specimen collection tube upright and unscrew 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 cassette, then start the timer. Avoid air bubbles. See illustration below.
- Wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
POSITIVE: Two distinct colored 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 hemoglobin 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 cassette. 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 and correct sample application to the specified specimen well. 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 Fecal Occult Blood Rapid Test Cassette (Feces) is for *in vitro* diagnostic use only.
- The Fecal Occult Blood Rapid Test Cassette (Feces) will only indicate the presence of human hemoglobin in the specimen, 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 Fecal Occult Blood Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test, demonstrating an overall accuracy of 98%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Fecal Occult Blood Rapid Test Cassette (Feces) has been compared to another leading commercial rapid test using clinical specimens. The results show that the relative sensitivity of the Fecal Occult Blood Rapid Test Cassette (Feces) is over 99.9%, and the relative specificity is 98.4%.

Method	Other Rapid Test		Total Results
	Positive	Negative	
Fecal Occult Blood Rapid Test Cassette	65	3	68
	0	182	182
Total Results	65	185	250

Relative Sensitivity: >99.9% (94.4%-100.0%)* Relative Specificity: 98.4% (95.3%-99.5%)*
Accuracy: 98.8% (96.5%-99.6%)* *95% Confidence Intervals

Analytical Sensitivity

The Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6µg hemoglobin/g feces.

Cross-Reactivity

The Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentrations were tested on both positive and negative controls with no effect on test results.

Substances	Concentrations (Diluted with the extraction buffer)
Bovine hemoglobin	1 mg/mL
Chicken hemoglobin	1 mg/mL
Pork hemoglobin	1 mg/mL
Goat hemoglobin	1 mg/mL
Horse hemoglobin	1 mg/mL
Rabbit hemoglobin	1 mg/mL

BIBLIOGRAPHY

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

Index of Symbols

	Manufacturer		Contains sufficient for <n> tests
	Consult instructions for use		<i>In vitro</i> diagnostic medical device
	Use-by date		Temperature limit
	Do not re-use		Catalogue number
	Batch code		Authorized representative in the European Community

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