FOB (Fecal Occult Blood) Rapid Test
(Feces – Cassette)
Product code: CTM-201

INTENDED USE

FOB Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces.

INTRODUCTION

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.

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

FOB Rapid Test Cassette (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.

MATERIALS SUPPLIED

1. Test cassette 2. Extraction buffer tube 3. Sampling swab
4. Instructions for use

MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection container 2. Timer

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.

WARNINGS AND PRECAUTIONS

- For professional 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

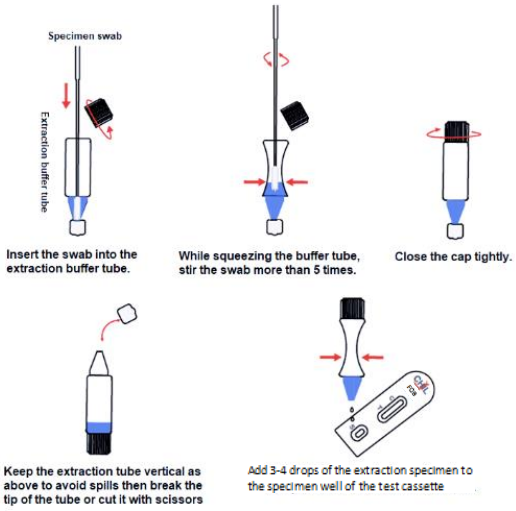
SPECIMEN COLLECTION

- 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.

TEST PROCEDURE

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

1. To collect fecal specimens:
   Collect feces in a clean, dry specimen collection container. The 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.
2. Remove the swab from the package. Make sure that do not touch the tip of the swab. Take a sample from at least 4 different parts of the fecal matter.
3. 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.
4. Follow the illustrations below for assay.
5. Read the results after 10 minutes. Avoid interpreting results after 15 minutes.

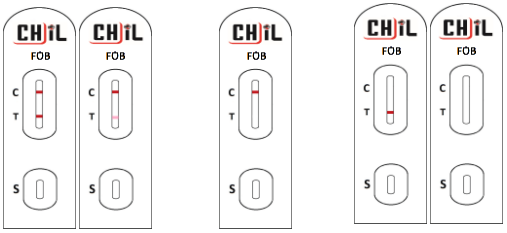


INTERPRETATION OF RESULTS

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.



Positive Negative Invalid

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 good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. FOB Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
2. 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.
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.

PERFORMANCE CHARACTERISTICS

Accuracy

FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Result
FOB Rapid Test Cassette (Feces)	Results	Positive	Negative	
	Positive	210	6	216
	Negative	12	850	862
Total Result		222	856	1078

Sensitivity: 94.6% Specificity: 99.3% Accuracy: 98.3%

Sensitivity

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

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 50ng/ml, 100ng/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: 50ng/ml, 100ng/ml and 10µg/ml positive specimens. Three different lots of the FOB Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

FOB Rapid Test Cassette (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 false results were observed on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

EXPECTED VALUES

FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test. The correlation between these two systems is 98.3%

REFERENCE

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.

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CE	CE marking	2°C 30°C	Storage temperature limitation
IVD	For in vitro diagnostic use		Expiry date
	Manufacturer		Consult Instruction for use
Σ	Test per kit		Do not re-use
LOT	Lot code		