todylaboratories®

Rapid Tests

CE IVD REF C61RT1015

FOB Rapid Test Cassette (Feces)
Package Insert

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 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, 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 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.

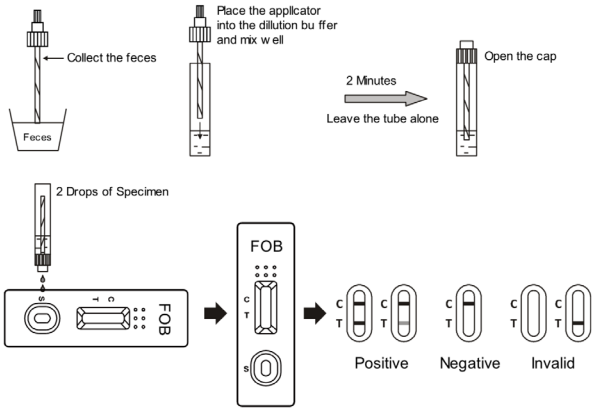
PRECAUTIONS
• For professional in vitro diagnostic use only. Do not use after expiration date.
• The test should remain in the sealed pouch until use.
• Do not eat, drink or smoke in the area where the specimens or kits are handled.
• Handle all specimens as if they contain infectious agents. Observe 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.

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 Cassettes • Package Insert • Specimen Collection Tubes with Extraction Buffer
Materials required but not provided
• Specimen Collection Containers • Timer • Droppers

DIRECTIONS FOR USE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. To collect fecal specimens:
Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). 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. For long term storage, specimens should be kept below -20°C.
2. To process fecal specimens:
• For **Solid 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 to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
• For **Liquid Specimens**:
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.
3. 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 alone for 2 minutes.
4. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) 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.
6. Read results at 5 minutes after dispensing the specimen. Do not read results after 10 minutes.
7. **Note**: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



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 Cassette (Feces) is for in vitro diagnostic use only.
2. 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.
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
The FOB Rapid Test Cassette (Feces) has been compared with another leading commercial rapid test. The correlation between this two system is 98.3%.

PERFORMANCE CHARACTERISTICS
Accuracy
The 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	189	4	193
	Negative	10	802	812
Total Result		199	806	1005

Relative sensitivity: 189/199=95% (95%CI*: 91%~97.6%);
Relative specificity: 802/806=99.5% (95%CI*: 98.7%~99.9%);
Accuracy: (189+802)/(189+10+4+802) =98.6% (95%CI*: 97.7%~99.2%).
*Confidence Intervals
Sensitivity
The 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
The 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 effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

BIBLIOGRAPHY
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.

todylaboratories®
Tody Laboratories Int. SRL
22 Vadul Moldovei, s1, OP 18, Bucharest, CP 014033, ROMANIA
+4021 269 00 00 +4021 269 06 41
ISO 15189, 17043, 9001, 13485
www.todylaboratories.com