RapidFor™ FOB Rapid Test Kit
Reference Number: VMD09

IVD IFU

INTENDED USE

The RapidFor™ FOB Rapid Test Kit İs a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces.

SUMMARY AND EXPLANATION

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.

The RapidFor™ FOB Rapid Test Kit 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 6μg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

MATERIALS AND COMPONENTS

Materials provided with the test kits

COMPONENT	20 Tests /box
Test Device	20 Test cassettes (1 Test/pouch x 20 pouches)
Buffer	20 single-use bottles, each with 1.5 mL extraction buffers
Packing Insert	1 instruction for use

Note: The components in different batches of the kit cannot be mixed.

PRINCIPLE OF THE TEST

The RapidFor™ FOB Rapid Test Kit 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.

STORAGE AND STABILITY

1.Store as packaged in the sealed pouch at temperature 2~30°C and relative humidity between 40%-60%. The kit is stable within the expiration date printed on the labeling.
2.The test cassette must be used within 15 minutes after removal from the foil pouch.
3.The kit must not be used after the expiry date. The expiry date is stated on the label/packaging.

SPECIMENT COLLECTION AND STORAGE

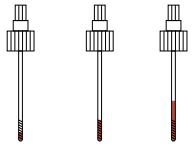
1.Specimens should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
2.Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
3.No dietary restrictions are necessary before using the test cassette.

WARNINGS AND PRECAUTIONS

1.For professional in vitro diagnostic use only. Do not use after expiration date.
2.The test should remain in the sealed pouch until use.
3.Do not eat, drink or smoke in the area where the specimens or kits are handled.
4.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.
5.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6.The used test should be discarded according to local regulations.
7.Humidity and temperature can adversely affect results.

TEST PROCEDURE

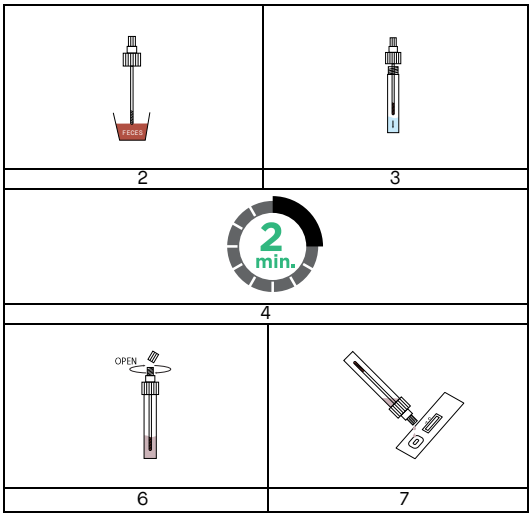
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. To collect fecal specimens:
Collect enough feces (1~2 mL or 1~2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay 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 80μL) into the specimen collection tube containing the extraction buffer.



3.Close the cap onto the specimen collection tube with extraction buffers, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
4. Leave the tube alone for 2 minutes.

Test Procedure

NOTE: Bring the pouch to room temperature before opening it.
NOTE: Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 15 minutes.
NOTE: Best results will be obtained if the test is performed immediately after opening the foil pouch.
5.Remove the test cassette from the foil pouch.
6.Hold the specimen collection tube upright and open the cap onto the specimen collection tube.
7.Invert the specimen collection tube and transfer 3 full drops of the extracted specimen to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S).
8.Read results at 5 minutes after dispensing the specimen. Do not read results after 15 minutes.
Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80μL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



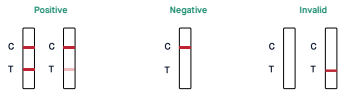
INTERPRETATION OF TEST RESULTS

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.



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.

PERFORMANCE CHARACTERIST

1. Accuracy

The RapidFor™ FOB Rapid Test Kit has been compared with another leading commercial rapid test using clinical specimens:

FOB Rapid Test Kit	Other Rapid Test Kit		
	Positive	Negative	Total
Positive	198	0	198
Negative	1	457	458
Total	199	457	656
Sensitivity: 99.49%			
Specificity: 100.0%			
Accuracy: 99.84%			

2. Sensitivity

The RapidFor™ FOB Rapid Test Kit can detect levels of Fecal Occult Blood as low as 50 ng/mL feces.

3. Precision

1) 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.

2) 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 RapidFor™ FOB Rapid Test Kit have been tested using these specimens. The specimens were correctly identified >99% of the time.

4. Cross-reactivity

The RapidFor™ FOB Rapid Test Kit 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.

LIMITATIONS

1. The RapidFor™ FOB Rapid Test Kit is for in vitro diagnostic use only.
2. The RapidFor™ FOB Rapid Test Kit 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.

SYMBOL USED

COMPONENT	Material Included
TEST CARD	Test Card
TUBE	Tube
IFU	Instruction for Use
	Consult Instruction for Use
2°C 30°C	Store at 2℃ ~ 30℃
	Expiration Date
	Manufacturer
	Keep Dry
LOT	Lot Number
DILUENT	Sample Buffer
	Date of Manufacture
	Do Not Reuse
REF	Reference Number
	Keep Away from Sunlight
Σ	Tests per Kit
IVD	In Vitro Diagnostic Medical Device
	Do not use if the package is damaged
%40 %60	Store between %40-%60 humidity
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

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Date of issue: 05.07.2023

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