FOB Rapid Test Kit
Reference Number: VMD09

IVD IFU CE

INTENDED USE
The FOB Rapid Test Kit is 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 Test/box
Test Device	20 Test cassettes (1 Test/pouch x 20 pouches)
Buffer	20 single-use bottles filled with 1.5 mL extraction buffer
Sample collection apparatus	20 single-use sample collection apparatus
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.

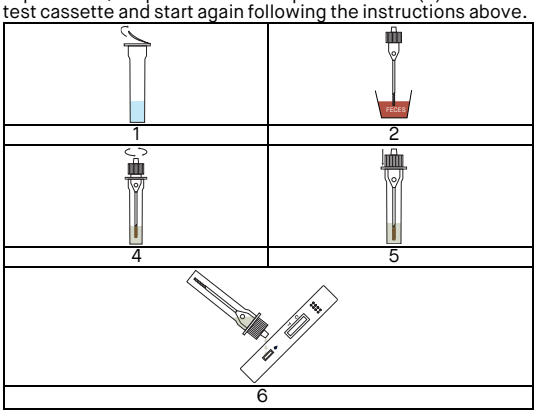
WARNINGS AND PRECAUTIONS
1.For professional in vitro diagnostic use only. Do not use after expiration date.
2.The test should remain in the sealed pouch until use.
3.Do not eat, drink or smoke in the area where the specimens or kits are handled.
4.Handle all specimens as if they contain infectious agents. 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) before testing.
To collect stool specimens:
Collect an adequate amount of feces (1~2 mL) in a clean, dry specimen collection container to obtain maximum antigen (if present). Best results will be obtained if the assay is performed within 6 hours after collection. If collected samples are not tested within 6 hours, they can be stored at 2~8°C for 3 day. For long-term storage, samples should be kept below -20°C.

1. Uncap the tube containing buffer solution and place on a flat surface.
2. Take the specimen collection apparatus and collect approximately 50 mg of stool (equivalent to 1/4 of a pea) by randomly stabbing the stool specimen in at least 3 different places. Do not scoop the stool sample.

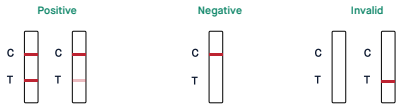
3. Place the sample collection apparatus into the tube containing the buffer solution.
4. Swirl the apparatus 15 times in the solution to dissolve the sample in the buffer solution.
5. After the sample and buffer solution are completely mixed, press the apparatus down to seal the tube.

Test Procedure
NOTE: Bring the package to room temperature before opening.
NOTE: Do not open the package until you are ready to test and it is recommended that the disposable test be used within 15 minutes under low ambient humidity (RH≤70%).
NOTE: Best results are obtained if the test is performed immediately after opening the foil pack.
6.Remove the test cassette from the foil pack.
7.Hold the sample-buffer solution mixing tube upright.
8.Invert the sample-buffer solution mixing tube and transfer 3 full drops of the extracted sample to the sample well (S) of the test cassette, then start the timer.
NOTE: Avoid air bubbles in the sample well (S).
9.Read results 5 minutes after the sample-buffer solution mixture is added to the test cassette. Do not read results after 15 minutes.
NOTE: If the specimen does not migrate on the test cassette (presence of particles), centrifuge the extracted specimens contained in the buffer solution vial. Collect 80µL of supernatant, dispense into the specimen well (S) of a new test cassette and start again following the instructions 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.



PERFORMANCE CHARACTERIST
Clinical Evaluation
The 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%			

Limit of Detection (LOD)
The FOB Rapid Test Kit can detect levels of fecal occult blood as low as 50 ng/mL feces.

Cross-reactivity
The test shows no cross reactivity with the below listed hemoglobin at given concentration.

No	Hemoglobin	Concentration
1	Bovine hemoglobin	1.0 ng/mL
2	Chicken hemoglobin	1.0 ng/mL
3	Pork hemoglobin	1.0 ng/mL
4	Horse hemoglobin	1.0 ng/mL
5	Rabbit hemoglobin	1.0 ng/mL
6	Turkey hemoglobin	1.0 ng/mL

LIMITATIONS
1. The FOB Rapid Test Kit is for in vitro diagnostic use only.
2. The 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°C ~ 30°C
	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: 17.11.2023

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