Fecal Occult Blood Test (FOB)

(Feces)

IVD CE

PRODUCT CODE
RT005

INTENDED USE:
Fecal Occult Blood (FOB) Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories. it is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. (FOB) is recommended for use in routine physical examinations, hospital monitoring for bleeding in patients and screening for colorectal cancer or gastrointestinal bleeding from any source.

CLINICALLY SIGNIFICANT:
Most of diseases can cause hidden blood in the stool. 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 method lacks sensitivity and specificity, and has diet-restriction prior to the testing. The Fecal Occult Blood (FOB) Rapid Test Devices (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6µg 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 (FOB) Rapid Test Device (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated with anti-hemoglobin antibodies. 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 proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED:
1. Test Devices 2. Desiccant 3. Package Insert 4. Specimen collection tube with extraction buffer

ADDITIONAL REQUIREMENTS:
1. Clock or Timer
2. Specimen collection containers.

REAGENT STORAGE AND STABILITY:
1. Store at 2℃ to 30℃ in the sealed pouch up to the expiration date. If stored at 2°C-8°C ensure that the test device is brought to room temperature before opening.
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Preferably open the pouch shortly before the test.

The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

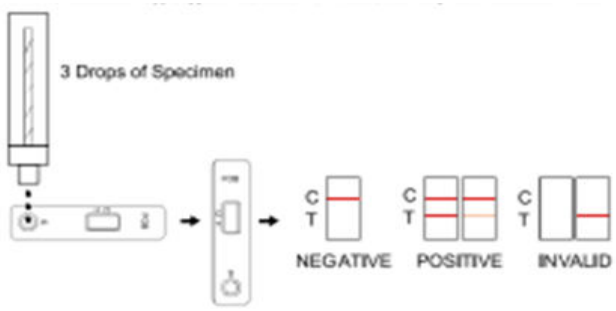
SPECIMEN AND SAMPLE PREPARATION:
1. All reagents are ready to use as supplied.
2. Store unused test device unopened at 2˚C-30˚C.
3. If stored at 2˚C-8˚C ensure that the test device is brought to room temperature before opening.
4. The test is not stable out of the expiration date printed on the sealed pouch.
5. Do not freeze the kit or expose the kit over 30˚C.

PRECATIONS:
1. For professional in vitro diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test result.
3. Do not use it if the tube /pouch is damage or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Do not use specimen with visible blood for the testing.
6. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contain Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. Electric fan or strong air conditioning.

PATIENT PREPARATION:
1. Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids, constipating bleeding or blood in the urine.
2. Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation and subsequent bleeding resulting, thus give positive reactions on the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.
3. Dietary restrictions are not necessary

PROCEDURE:
1. Allow test device, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. To collect fecal specimens:
   - Collect feces in a clean, dry specimen collection container.
   - Unscrew the cap of the specimen collection tube and remove the applica tor stick.
   - transfer Randomly small portion of stool specimen in at least 5 different sites into the sample diluent.
   - Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
   - replace the stick in the tube and tighten securely, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.

   Note: Specimens collected may be stored at least eight (8) days at room temperature below 35˚C, six (6) months at 2°C-8°C and two (2) years at <-20 °C
3. Remove the test device from the sealed pouch and use it as soon as possible.
4. Place the test device on a clean, flat surface.
5. Shake the sample collection device several times.
6. Holding the sample collection device upright, carefully break off the tip of collection device.
7. transfer 2-3 full drops of the extracted specimen (approx. 90 µL) to the specimen well of the test device, and then start the timer.
8. Wait for the colored line to appear. Read result in 5 minutes. Do not interpret the result after 5 minutes



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RESULTS:
POSITIVE: Two lines appear. One colored line should be in the control region (C) and another apparent colored line should be in the test region (T).
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).
INVALID: Control line fails to appear. The test should be repeated using a new strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
NOTE:
- The intensity of color in the test line region (T) will vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive.
- insufficient specimen volume, incorrect operating procedure or expired test are the most likely reasons for control band failure
- if the test line is weak, it is recommended that the test be repeated in 48 hours

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, adequate membrane wicking and correct procedural technique.
The Controls are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS:
Sensitivity:
The Fecal Occult Blood (FOB) Rapid Test device (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or around 6µg hemoglobin/g feces.
Prozone effect:
It is observed that this FOB test can detect 2 mg/ml hemoglobin.
Specificity:
The Fecal Occult Blood (FOB) Rapid Test device (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration were tested on both positive and negative controls with no effect on test results on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Horse hemoglobin	20 mg/ml
Chicken hemoglobin	0.5 mg/ml
Goat hemoglobin	0.5 mg/ml
Rabbit hemoglobin	0.06 mg/ml
Beef hemoglobin	2 mg/ml
Pig hemoglobin	0.5 mg/ml

SYMBOLS OB LABEL

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCE

1. Simon J.B. Occult Blood ScreeningforColorectal Carcinoma: A Critical Review,Gastroenterology, Vol. 1985; 88: 820.
2. Blebea J. and Ncpherson RA. False-PositiveGuaiac Testing With Iodine, ArchPathol LabMed, 1985;109:437-40

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