

Fecal Occult Blood (FOB) Rapid Test Device (Feces)

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 or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. Fecal Occult Blood (FOB) Rapid Test Device (Feces) is recommended for use in 1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

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. Fecal Occult Blood (FOB) Rapid Test Device (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 50ng/mL of hemoglobin or hcg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

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 antibodies 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 antibodies 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 PROVIDED

1. Test devices
2. Desiccant
3. Specimen collection tube with extraction buffer
4. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or Timer

STORAGE AND STABILITY

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

PRECAUTIONS

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 results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Tests 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 contains 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 assayed.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, i.e. electric fan or strong airconditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:
 - Menstrual bleeding
 - Bleeding hemorrhoids
 - Constipating bleeding
 - Urinary bleeding
2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, corticosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

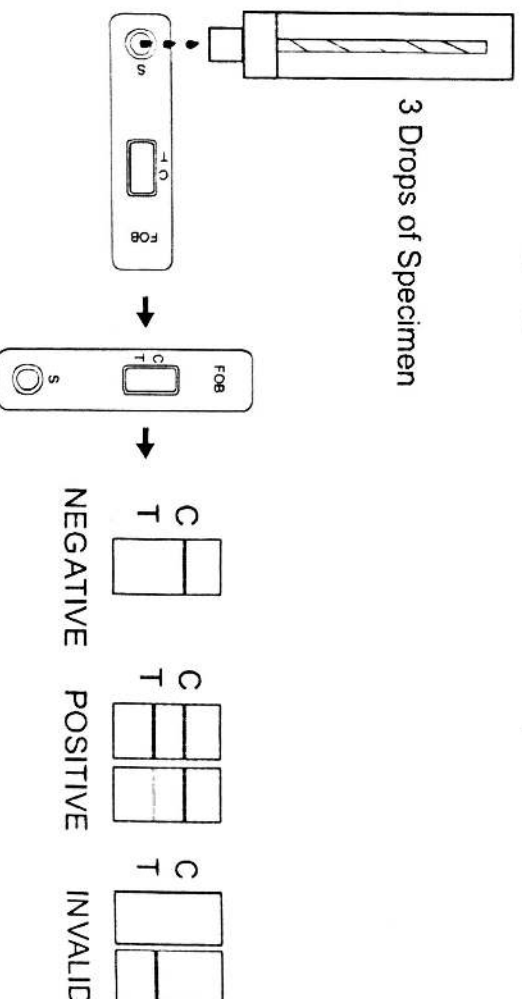
SPECIMEN COLLECTION AND PREPARATION

- Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
1. Collect a random sample of feces in a clean, dry receptacle.
 2. Unscrew the top of the collection tube and remove the applicator stick.
 3. Randomly pierce the fecal specimen in at least five (5) different sites.
 4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
 5. Replace the stick in the tube and tighten securely.
 6. Shake the specimen collection bottle so that there is proper homogenisation of faeces in buffer solution.
- 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.

TEST PROCEDURE

- Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
 2. Place the test device on a clean, flat surface.
 3. Shake the sample collection device several times.
 4. Holding the sample collection device upright, carefully break off the tip of collection device.
 5. Squeeze 3 drops (~90µL) of the sample solution in the sample well of the cassette and start the timer.
 6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.

3 Drops of Specimen



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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).
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. 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:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids, or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Tract.
7. The Fecal Occult Blood (FOB) Rapid Test Device (Feces) is to aid in diagnosis and is not intended to replace other diagnostic procedures such as GI, fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** Fecal Occult Blood (FOB) Rapid Test Device (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6µg hemoglobin/g feces.

2. **Prozone Effect:**

It is observed that this FOB test can detect 2mg/ml hemoglobin.

3. **Specificity:**

Fecal Occult Blood (FOB) Rapid Test Device (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

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

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma. A Critical Review, Gastroenterology, Vol. 1985, 88: 820.
2. Blebea J. and Nepherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985, 109:437-40