

FECAL OCCULT BLOOD (FOB) CARD

IMMUNOPAK

[Stool]

Last update 10-2020

Ref. RDT-FOB.109, 10 Test

INTENDED USE

Rapid Fecal Occult Blood (FOB) Card Test is an immunochromatographic assay intended for the determination of human hemoglobin in faeces by professional laboratories or physician's offices. It is useful to determine gastrointestinal bleeding, founding a number of gastrointestinal disorders such as colorectal carcinoma, colon polyps, diverticulitis and ulcerative colitis.

Rapid Fecal Occult Blood (FOB) Card Test is recommended for use in 1) routine physical examination, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

The presence of hemoglobin in faeces can be indicative of gastrointestinal tract conditions associated with bleeding such as colorectal carcinoma, colon polyps, Crohn's disease, and ulcerative colitis.

Rapid Fecal Occult Blood Test is designed to detect lower levels of Fecal occult blood than standard guaiac tests. The basis of the test is an immunochromatographic sandwich capture method, which yields results more specific to human hemoglobin and are easier to interpret than those of guaiac-based devices.

PRINCIPLE

The FOB Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of Human Occult Blood in faeces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with anti-hemoglobin antibody colloidal gold conjugate. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a pink-purple line. The presence of this pink-purple line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	10 Tests
FOB Test Cards	10 cards
Sample Collection Tubes with Buffer	10 tubes
Product Package Insert	1 nos.

STORAGE AND STABILITY

FOB test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

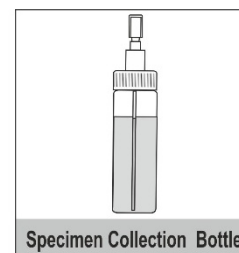
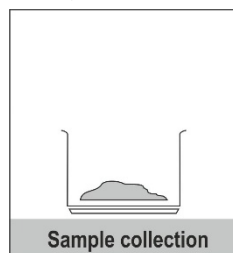
1. For *in vitro* diagnostic use only.
2. Do not use product beyond the expiration date.
3. Patient samples may contain infectious agents and should be handled accordingly. Dispose of all used test components in a biohazard container.

PATIENT LIMITATIONS

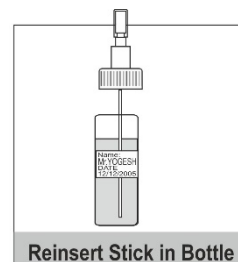
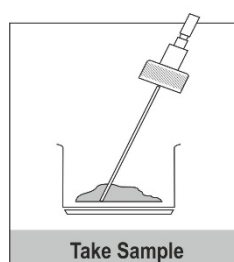
1. Specimen should not be collected from a patient with the following conditions that may interfere with test results:
 - Menstrual bleeding
 - Bleeding hemorrhoids
 - Constipation bleeding
 - Urinary bleeding
2. Alcohol and certain medications such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroidal and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding in some patients.

SPECIMEN COLLECTION AND STORAGE

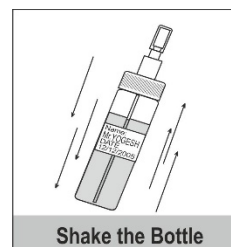
1. Use human faeces as specimen.
2. Collect faeces in a clean dry container.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hr.
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. Label the specimen collection bottle with specimen identity.



6. Unscrew and remove the cap (with attached sampling stick) of the specimen collection bottle ensuring that the extraction buffer is not spilt.
7. Take representative amounts of faeces specimen from different portions of the sample by introducing the sampling stick at 3-4 different places in the faeces specimen.



8. Wipe the sampling stick with an absorbent or tissue paper. The sample taken up by the grooves is sufficient for the test.
9. Reinsert the sampling stick into the bottle and screw the cap tightly.
10. Shake the specimen collection bottle so that there is proper homogenisation of faeces in buffer solution.



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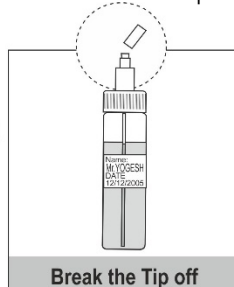
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TEST PROCEDURE

1. Bring the kit components of device to room temperature prior to testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device. Once opened, the device must be used immediately.
4. Place the testing device on a flat horizontal surface.
5. Hold the specimen collection bottle in an upward position and break the tip off.



6. Invert the bottle and holding the dropper vertically, carefully dispense exactly two drops of specimen-buffer mixture into the specimen port.
7. Results can be read in 10 minutes after adding the specimen. Positive results can be visible in as short as 5 minutes.
8. Do not read and interpret after 10 minutes.
IMPORTANT: The result must be interpreted between 5 and 10 minutes. Waiting more than ten minutes may cause the reading to be inaccurate.

INTERPRETATION OF RESULTS

- **Negative:** Only one pink-purple line appears on the control (C) region. No apparent line on the test (T) region.
- **Positive:** In addition to a pink-purple control (C) line, a distinct pink-purple line will also appear in the test (T) region.
- **Invalid:** A total absence of pink-purple line in both regions or no pink-purple line appears on the control (C) region is an indication of procedure error and / or the test reagent deterioration. Repeat the test with a new test cassette.
Note: Specimens containing very low levels of human hemoglobin may develop two pink-purple line over 10 minutes.

LIMITATIONS

1. As with any diagnostic test, Rapid Fecal Occult Blood test may not be considered as a conclusive diagnosis for gastrointestinal bleeding or pathology. It is not intended to replace other diagnostic procedures such as G.I. fibro scope, endoscopy, colonoscopy or other x-ray analysis.
2. Although the test is very accurate in detecting human hemoglobin, there is a possibility false result may occur. In addition, because many bowel lesions, including some colorectal cancers and polyps, may bleed intermittently or not at all, occult blood may not be uniformly distributed throughout the faeces sample. Thus test results may be negative even when disease is present.
3. Rapid Fecal Occult Blood Test has not been tested for toilet water interference and that samples that have touched the toilet water should not be used for testing.
4. Rapid Fecal Occult Blood Test has not been tested on abnormal blood from Thalassemia and Sickle Cell patients.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** The analytical sensitivity of the test is 50ng hHb/ml buffer or 5 ug hHb/g feces.
2. **Accuracy:** There were 120 human hemoglobin free feces extraction specimens collecting over 10 days from in house and grouped these samples into 6 in an evenly distributed number 20. The 6 groups of extraction samples were spiked with human hemoglobin for six different concentrations, respectively, 0ng/ml; 20ng/ml; 40ng/ml; 50ng/ml; 100ng/ml; 2000ng/ml. The results obtained agreement 98% with the predicate device.
3. **Specificity:** Rapid Fecal Occult Blood Test is specific to human hemoglobin. Specimens containing the following substances have no effect on test result:

Substance	Concentration
Chicken Hemoglobin	500 ug/ml
Pork Hemoglobin	500 ug/ml
Beef Hemoglobin	500 ug/ml
Goat Hemoglobin	500 ug/ml
Horse Hemoglobin	500 ug/ml
Rabbit Hemoglobin	500 ug/ml
Horseradish Peroxidase	2000 ug/ml

INTERFERENCE TESTING

The following substances were added to human hemoglobin free and 50 ng hHb/ml controls. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Ampicillin	40 mg/dl
Ascorbic acid	40 mg/dl
Atropine	40 mg/dl
Caffeine	40 mg/dl
Gentisic acid	40 mg/dl
Glucose	2000 mg/dl
Human albumin	2000 mg/dl

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