

# One Step Fecal Occult Blood Rapid Test

For detection of human hemoglobin from blood in fecal.



In-vitro diagnostic use only



Not reuse

## Introduction

Many diseases may result in hidden blood in the feces. This is 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 of occult blood testing lack sensitivity and specificity, and also require diet restrictions prior to testing. Fecal occult blood tests are used as a screening tool for detecting lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, peptic ulcer, ulcerative colitis, polyps, and colorectal cancer. The FOB Test Device is recommended for use by health professionals in routine physical examinations and in monitoring for GI bleeding in patients in hospitals or in physicians' offices. The Fecal Occult Blood Test is a simple, visual qualitative test that detects human hemoglobin from blood in fecal. The test is based on immunochromatography and can give a result within 5 minutes.

## Intended Use

The Fecal Occult Blood Test (FOB Test) is a rapid chromatographic immunoassay for the qualitative detection of human hemoglobin from blood in fecal.

## Principle

The Fecal Occult Blood Test is a qualitative membrane strip based immunoassay for the detection of human hemoglobin from blood in fecal. In this test procedure, anti-hemoglobin antibody is immobilized in the test line region of the device. After an adequate volume of test specimen is placed in the specimen well, it reacts with hemoglobin antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized hemoglobin antibody. If the specimen contains hemoglobin antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain hemoglobin antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C.

## Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

## Specimen Collection, Storage and Precautions

1. The Fecal Occult Blood Test can be performed used on feces.
2. Collect sufficient quantity of 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 assays performed within 6 hours after collection.
3. 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.
4. 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.
5. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

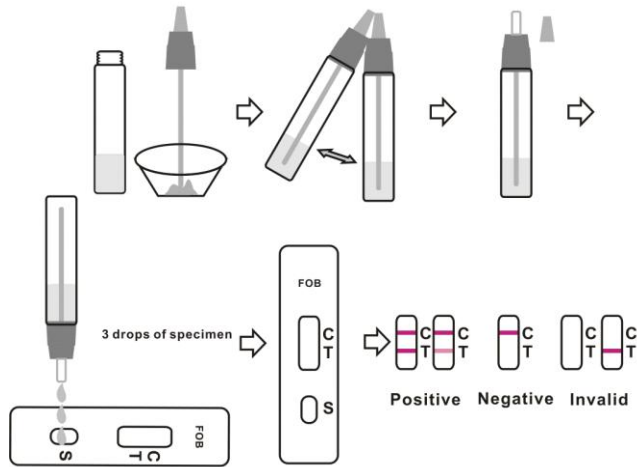
## Test Procedure (Refer to Figure)

Allow the test, specimen and/or controls to reach room temperature 15-30 °C prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
3. Holding the sample collection tube upright, carefully take off the tip of collection tube, transfer 3 drops (approximately 100µl) to the specimen well(S) of the test device, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

### Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of specimen to the specimen well.



## Interpretation of Test Results (Refer to Figure)

**Positive:** Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

**Negative:** One colored line appears in the control region(C).No apparent colored line appear in the test line region.

**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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## Limitations of the Test

1. The Fecal Occult Blood Test is for in vitro diagnostic use only. The test should be used for the detection of human hemoglobin from blood in fecal only. Neither the quantitative value nor the rate of increase in hemoglobin can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

## Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

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