

# One Step Fecal Occult Blood Test Device (Feces)

**Specimens:** Feces

**For professional in vitro diagnostic use only.**

## INTENDED USE

The FOB Rapid Test Device is a rapid visual immunoassay for the qualitative presumptive detection of human hemoglobin in human fecal specimens. This kit is intended to be used as an aid in the diagnosis of lower gastrointestinal (g.i.) pathologies.

## INTRODUCTION

Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer death in the United States. Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality.

Earlier commercially available FOB tests utilized the guaiac test, which requires special dietary restriction to minimize false positive and false negative results. The FOB Rapid Test Device (Feces) are especially designed to detect human hemoglobin in fecal samples using immunochemical methods, which improved specificity for the detection of lower gastrointestinal disorders, including colorectal cancers and adenomas.

## PRINCIPLE

The FOB Rapid Test Device (Feces) has been designed to detect human hemoglobin through visual interpretation of color development in the internal strip. The membrane was immobilized with anti-human hemoglobin antibodies on the test region. During the test, the specimen is allowed to react with colored anti-human hemoglobin antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough human hemoglobin in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

## KIT COMPONENTS

<b>Individually packed test strips</b>	Each strip contains colored conjugates and reactive reagents pre-spread at the corresponding regions.
<b>Specimens' dilution tube with buffer</b>	0.1 M Phosphate buffered saline (PBS) and preservative
<b>Package insert</b>	for operation instruction.
	sealed pouch, and place it on a clean, level surface. Label the test

## MATERIALS REQUIRED BUT NOT PROVIDED

<b>Specimen collection container</b>	For specimens collection use.
<b>Timer</b>	For timing use.
<b>Centrifuge</b>	For treatment of special specimens.

## PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents.

It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).

- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.

- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for

regulations.

## STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

## SPECIMEN COLLECTION AND STORAGE

The FOB Rapid Test Device (Feces) is intended only for use with human fecal specimens.

- Patients should not collect samples during or within 3 days of their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.
- 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.
- No dietary restrictions are necessary before testing.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

## PROCEDURE

**Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.**

- Specimen collection and pre-treatment:
  - Use the specimen collection container for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.
  - Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
  - Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
  - Shake the specimen collection tube vigorously to mix the specimen and the extraction

buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.	<b>Relative Specificity:</b> 98.5% (97.7%-99.2%)*			
2. Testing	<b>Overall Agreement:</b> 98.2% (97.5%-98.9%)*			
	<b>*95% Confidence Interval</b>			
1) Remove the test from its with patient or control identification. To obtain a best result, the assay should be performed within one hour.		341	1033	1374

### A. Analytical Sensitivity

- Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and **dispense 3 drops of solution** into the specimen well (S) of the test device. **Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.** As the test begins to work, you will see color move across the membrane.
- Wait for the colored band(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 10 minutes.

## INTERPRETATION OF RESULTS

### POSITIVE RESULT:

proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable

C T

### NEGATIVE RESULT:

C T

substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.

- Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 OF THE TEST

- The FOB Rapid Test Device (Feces) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of human hemoglobin only.
- The presence of blood in stools may be due to several causes, besides colorectal bleeding, such as hemorrhoid, blood in urine or stomach irritations.
- 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.
- Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.
- This test may be less sensitive for detecting upper g.i. bleeding because blood degrades as it passes through the g.i. track.
- All colorectal bleedings may not be due to precancerous or cancerous polyps. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

## PERFORMANCE CHARACTERISTICS

	FOB Rapid Test		
	+	-	Total
<b>Relative Sensitivity:</b> 97.3% (95.6%-99%)*			
	+	334	
Other		1040	
RT	-		

A sample containing human hemoglobin at concentration equal to or higher than 40 ng/ml produces a positive result. In some cases sample containing human hemoglobin at concentrations less than 40 ng/ml can also be tested as positive.

### Hook or Prozone effect:

Sample containing as high as 0.5 mg/ml hemoglobin can still test positive. The tests do not show a Hook or Prozone Effect up to the maximal observed physiological concentration (0.5 mg/ml). Thus, the working range is 40 ng/ml up to 0.5 mg/ml.

### B. Analytical Specificity:

The test is specific for human hemoglobin and does not show any cross-reaction with the hemoglobin from bovine, pig, horse and sheep concentrations up to 0.5 mg/ml.

\* A colored band appears in the control band region (C) and another colored band appears in the T band region.

One colored band appears in the control band region (C). No band appears in the test band region (T).

gloves and eye protection when specimens are assayed.

- Buffered Saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.

- The used testing materials should be discarded in accordance with local, state and/or federal

**Hemoglobin from rabbit and polecat may cause crossreactions.**

The test also does not show any cross reaction with bilirubin, vitamin C and horse radish peroxidase.

**C. Clinical Specificity:**

The following non-cancer related factors may cause blood in feces samples:

**1) Iron**

Food supplementation with iron leads to increased release of blood in the colon. Iron itself is not cross-reacting with the test.

**2) Acetylsalicylic acid**

**NOTE:**

**INVALID RESULT:**



Control band fails to appear. Results from any test which has not

C T

produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

ASA is main compound in a lot of drugs against headache (e.g. Aspirin® from Bayer), and is

sometimes used to substitute macumar as a blood diluter. Almost always there are very small amounts of blood in fecal samples in case of healthy humans. This is far below the sensitivity of our test and has nothing to do with cancer or any other serious matter. If a patient takes blood diluters bleeding can be more intensive. Therefore the cut-off of the test may be reached.

**3) Coumarin**

Coumarines are used as drugs (e.g. Macumar®) for prevention of heart attacks, against thrombosis

and stroke. Similar to ASA, coumarins are blood diluter. Almost always there are very small amounts of blood in fecal samples in case of healthy humans. This is far below the sensitivity of the test and has nothing to do with cancer or any other serious matter. If a patient takes blood diluters, bleeding can be more intensive. Therefore, the cut-off of the test may be reached.

**4) Hemorrhoids**

Hemorrhoids may bleed. Therefore, fecal sample may be contaminated with blood which is not associated with cancer.

**5) Monthly period**

Small amounts of blood released because of female's period may contaminate the fecal sample. This is blood which is not associated with cancer.












**6) Urine samples**

Several diseases may cause blood in urine samples. To avoid detection of urine-related blood, stool sample should not get in contact with urine.

**LITERATURE REFERENCES**

1. Dam, J.V., et. al.; Fecal Blood Screening for Colorectal Cancer; Archive of Internal Medicine; (1995) 155:2389-2402.
2. Frommer, D.J. et. al.; Improved Screening for Colorectal Cancer by Immunological Detection of Occult Blood; British Medical Journal; (1988) 296:1092-1094.
3. Lieberman, D.; Screening/Early Detection Model for Colorectal Cancer; Why Screen? Cancer Supplement; (1994) 74(7):2023-2027.
4. Miller, A.B.; An Epidemiological Perspective on Cancer Screening; Clinical Biochemistry (1995) 28(1): 41-48.
5. Ransohoff, D.F. and Lang, C.A.; Improving the Fecal Occult-Blood Test; The New England Journal of Medicine; (1996) 334 (3):189-190.
6. Screening for Colorectal Cancer-United States, 1992-1993, and New Guidelines; Mobility and Mortality Weekly Report; (1995) 45 (5): 107-110.
7. St. John, D.J.B., et al.; Evaluation of New Occult Blood Test for Detection of Colorectal Neoplasia; Gastroenterology; (1993) 104:1661-1668.
8. Yamamoto M., Nakama H., Cost-effectiveness analysis of immunochemical occult blood screening for colorectal cancer among three fecal sampling methods: Hepatogastroenterology, 2000 Mar-Apr; 47 (32) 396-399.

**INDEX OF SYBOML**

	Consult instructions for use		Keep dry
	Temperature limit		Batch code
	Do not re-use		In vitro diagnostics medical device
	Manufacturer		Date of Manufacture
	Use-by date		contains sufficient for <n> tests
			Keep away from sunlight



Sirin Diagnostics  
 20/213rd Industrial Sector – 2nd Cell –  
 El-Matahra Industrial City - Minia – Egypt