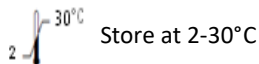


## Fecal Occult Blood Test Strip (Feces)

**IVD** For In-Vitro diagnostic and professional use only



### INTENDED USE

The FOB One Step Fecal Occult Blood Test Strip (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces.

### 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. The FOB One Step Fecal Occult Blood Test Strip (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 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 FOB One Step Fecal Occult Blood Test Strip (Feces) is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the Strip. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. 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

#### MATERIALS PROVIDED

- Test Strip (contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane).
- Specimen collection tube with extraction buffer.
- Package insert.

#### MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Timer.
- Pipette.

### PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

### STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Strip is stable through the expiration date printed on the sealed pouch.
- The test Strip must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

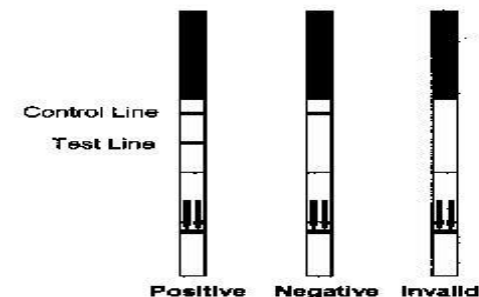
### PATIENT PREPARATION

- Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
- 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.
- Dietary restrictions are not necessary.

### PROCEDURE

1. Allow the test strips and samples to reach room temperature (15-30°C) prior to testing. Do not open the package until ready to perform the assay.
2. Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent.
3. Shake gently in order to unstuck and facilitate the sample dispersion.
4. Hold the vial and break the tip off.
5. Dispense 10 drops (approximately 0.5 ml) of the sample extract in a test tube.
6. Immerse the test strip in the liquid prepared in step 5. Do not exceed the line shown on the strip.
7. Read the result 5 minutes after the immersion of the strip. Do not read result after 10 minutes.

**INTERPRETATION OF RESULTS** (Please refer to the illustration below)



**POSITIVE:\***

**Two distinct red lines appear.** One line should be in the control region (C) and another line should be in the test region (T).

**\*NOTE:**

The intensity of the red color in the test line region (T) will vary depending on the concentration of hemoglobin present in the specimen. Therefore, any shade in the test region indicates positive result.

**NEGATIVE:**

**One red line appears in the control region (C).** No apparent red or pink line appears in the test region (T).

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

**EXPECTED VALUES**

The FOB One Step Fecal Occult Blood Test Strip (Feces) has been compared with another leading commercial rapid test. The correlation between these two systems is 98%.

**QUALITY CONTROL**

- A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume 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.

**LIMITATION**

- The FOB One Step Fecal Occult Blood Test Strip (Feces) is for *in vitro* diagnostic use only.
- The FOB One Step Fecal Occult Blood Test Strip (Feces) will only indicate the presence of human

hemoglobin in the specimen and the presence of blood in feces may be other than colorectal bleeding.

- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.

**PERFORMANCE CHARACTERISTICS****Sensitivity**

The FOB One Step Fecal Occult Blood Test Strip (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or around 2µg hemoglobin/g feces.

**Specificity**

The FOB One Step Fecal Occult Blood Test Strip (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.

Substances	Concentrations (Diluted with the extraction buffer)
Bovine hemoglobin	1 mg/mL
Chicken	1 mg/mL
Pork hemoglobin	1 mg/mL
Goat hemoglobin	1 mg/mL
Horse hemoglobin	1 mg/mL
Rabbit hemoglobin	1 mg/mL
Turkey hemoglobin	1 mg/mL

**REFERENCES**

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

**ATLAS MEDICAL**  
Ludwig-Erhard Ring 3  
15827 Blankenfelde-Mahlow

















Germany

Tel: +49 - 33708 – 3550 30

Email: Info@atlas-medical.com

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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry