

TEST MONOFASE SANGUE OCCULTO FECALE
ONE STEP FECAL OCCULT BLOOD TEST DEVICE (FECES)
1 ETAPE TEST DE SANG OCCULTE FÉCAL SUR CASSETTE (FÈCES)
EINSTUFEN FÄKALES OKKULTES BLUT TESTKASSETTE (STUHL)
PRUEBA DE SANGRE OCULTA FECAL EN UN SOLO PASO
EN PLACA (HECES)
DISPOSITIVO PARA TESTE DE SANGUE OCULTO
EM UM SÓ PASSO (FEZES)
ΣΥΣΤΗΜΑ ΕΝΟΣ ΣΤΑΔΙΟΥ ΤΕΣΤ ΚΡΥΦΟΥ ΑΙΜΑΤΟΣ (ΚΟΠΡΑΝΩΝ)
فحص أحادي الطور لكشف الدم الخفي الغائطي

PER USO PROFESSIONALE
FOR PROFESSIONAL USE

Manuale d'uso - User manual - Manuel de l'utilisateur - Gebrauchsanweisung
Guia de Uso . Guia para utilização - Instrukcja obsługi
Οδηγίες χρήσης - دليل الإستعمال والرعاية

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ACHTUNG: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

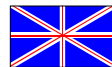
ATENÇÃO: Os operadores devem ler e entender completamente este manual antes de usar o produto

ΠΡΟΣΟΧΗ: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εννείοιδίου πριν από την χρήση του.

الحذر: على العمال قراءة وفهم هذا الدليل بكامله قبل البدء باستخدام المنتج.



REF 24530



One Step Fecal Occult Blood Test Device (Feces)

A rapid, one step test for the qualitative detection of Human Occult Blood in feces. For professional in vitro diagnostic use only.

INTENDED USE

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

SUMMARY

Many diseases can cause hidden blood in the feces. This is also 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 lack sensitivity and specificity, and also have diet restrictions prior to testing.^{1,2} The FOB One Step Fecal Occult Blood Test Device (Feces) is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50 ng/mL or higher, or 6 µg/g feces. In addition, unlike 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 Device (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 test. 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 line 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 the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.



STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Specimens 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.
- No dietary restrictions are necessary before using the FOB One Step Fecal Occult Blood Test Device (Feces).

MATERIALS

Materials Provided

- Test devices
- Specimen collection tubes with extraction buffer
- Package insert

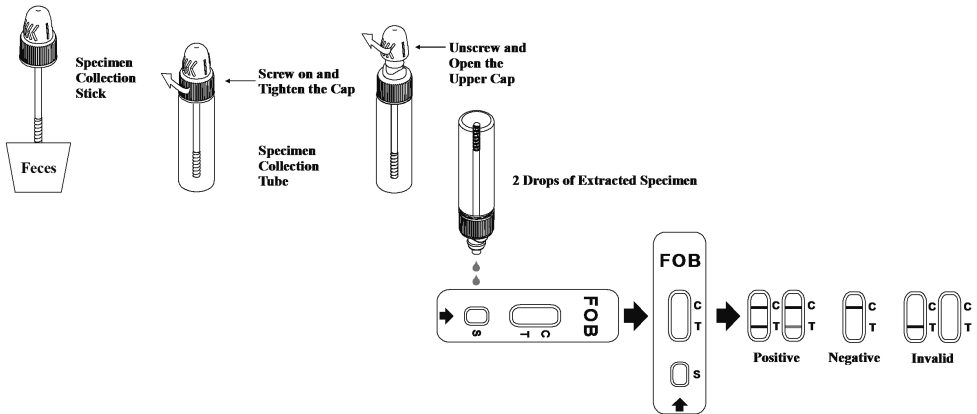
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow test, specimen collection tube, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. To collect fecal specimens: Collect feces in a clean, dry specimen collection container. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours.
2. To process fecal specimens: Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection stick into the fecal specimen in at least 3 different sites. Do not scoop the fecal specimen. Screw on and tighten the cap onto the specimen collection tube, then 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.
3. Remove the test device from the sealed pouch and use it as soon as possible.
4. Hold the specimen collection tube upright and break off the tip of the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approx. 90µL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

***NOTE:** The intensity of color in the test line region (T) will vary depending on the concentration of Fecal Occult Blood present in the specimen. Therefore, any shade in the test region indicates positive result.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered 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. The FOB One Step Fecal Occult Blood Test Device (Feces) is for in vitro diagnostic use only.
2. The FOB One Step Fecal Occult Blood Test Device (Feces) will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

EXPECTED VALUES

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



PERFORMANCE CHARACTERISTICS

Accuracy

The FOB One Step Fecal Occult Blood Test Device (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Results
FOB One Step Test Device	Results	Positive	Negative	
	Positive	206	8	214
	Negative	14	847	861
Total Results		220	855	1075

Relative Sensitivity: 93.6% (89.6%- 96.5%)*

Relative Specificity: 99.1% (98.2%- 99.6%)

Relative Accuracy: 98.0% (96.9%- 98.7%)*

*95% Confidence Intervals













Sensitivity

The FOB One Step Fecal Occult Blood Test Device (Feces) can detect levels of Fecal Occult Blood as low as 50 ng/mL or 6 µg/g feces. Specificity The FOB One Step Fecal Occult Blood Test Device (Feces) is specific to human hemoglobin. Specimens containing the following substances were diluted in the extraction buffer to a concentration of 1.0 mg/mL, and tested on both positive and negative controls with no effect on test results: Bovine hemoglobin, Chicken hemoglobin, Pork hemoglobin, Goat hemoglobin, Horse hemoglobin, Rabbit hemoglobin and Turkey hemoglobin.

BIBLIOGRAPHY

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

Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30° C		Lot Number		Catalog 24530
	Keep away from sunlight		Keep in a cool, dry place		Please read instructions carefully