Fecal Occult Blood Rapid Test
Package Insert

Cat: DTS157 **Specimens:** fecal

For professional *in vitro* diagnostic use only.

INTENDED USE

The Creative Diagnostics FOB card test 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 Creative Diagnostics FOB card test 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 Creative Diagnostics FOB card test is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the device. 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.

PRODUCT CONTENTS

The Creative Diagnostics FOB card test contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

MATERIALS SUPPLIED

Each test contains :1. One cassette device
2. Specimen collection tube with extraction buffer
3. One desiccant

Each kit contains: 1. 20 test devices
2. One instruction

MATERIAL REQUIRED BUT NOT PROVIDED

Clock or Timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C.
If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.

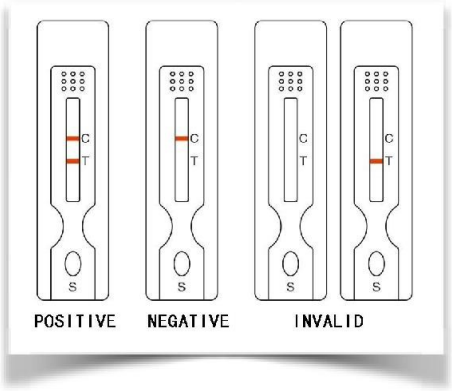
SPECIMEN COLLECTION

Collect stool sample by using the special sample collection device. First, unscrew the top of the sample collection device, take out the sample collection stick, and collect the sample by dipping the stick into 6 different places of the stool sample. Then, put the sample collection stick back in the sample collection device and screw together tightly.
Specimen should not be collected during or within three days of 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.

TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Shake the sample collection device several times.
4. Holding the sample collection device upright, carefully unscrew the small cap on the top of the collection device. Note this is a separate cap from the one used to collect specimen.
5. Squeeze 3 drops (~75uL) of the sample solution in the sample well of the cassette, as in the illustration.
6. Read the test results in 5 to 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes.

INTERPRETATION OF RESULTS



Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).The color intensity of the test line reflects the concentration level of Hb.
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear.

QUALITY CONTROL

A pink line appearing in the control region(C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls be tested at regular intervals as good laboratory testing process.
Users should follow the appropriate local guidelines concerning the running of external quality controls.

LIMITATIONS

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This test is limited to the detection of FOB in human stool sample only.
3. Although the test is highly accurate in detecting human hemoglobin, a low incidence of false positive results may occur. In addition, because many bowl lesions, indulging some polyps and colorectal cancers, may bleed intermittently or not at all, occult blood may not be uniformly distributed throughout a fecal sample. Thus rest results may be negative even when disease is present.

PERFORMANCE CHARACTERISTICS

Sensitivity: The Creative Diagnostics FOB card test can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6μg hemoglobin/g feces.
Specificity: The Creative Diagnostics FOB card test 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 hemoglobin	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

REFERRENCE

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

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

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CE FDA CLIA WAIVED