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Sağlık Ürünleri İç ve

Tell Me Fast Fecal Occult Blood (FOB) Test

INSTRUCTIONS FOR USE

INTENDED USE

Biocan Tell Me Fast One-Step Fecal Occult Blood (FOB) Test is a colloidal gold-antibody complex immunoassay for *in vitro* qualitative determination of FOB in feces at or above the cutoff of 30ng/ml. The test is intended for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. This FOB test device is recommended for use in (1) routine physical examinations, (2) monitoring any bleeding in patients, and (3) screening for colorectal cancer or gastrointestinal bleeding.It is intended for professional use as a tumor marker. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Tell Me Fast One-Step Fecal Occult Blood (FOB) Test is an immunochromatographic in vitro assay for qualitative determination of human hemoglobin in feces. Hemoglobin in feces is an indication of internal bleedings associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis and CROHN's disease. Colorectal cancer is the third most common cancer in the world. The appearance of occult blood in human fecal specimen is often associated with gastrointestinal diseases, which might cause colorectal cancer if not treated promptly and properly. Biocan Tell Me Fast One Step FOB Test uses immunochromatographic technique that is more sensitive and more specific than the traditional guaiac assay does, and easier to interpret the result. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients. Tell Me Fast One Step FOB Test is composed of two units, a fecal collection tube and a test device. Fecal specimen is collected in the collection tube containing sample extraction buffer and then added to the test device. When the sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-h hemoglobin antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-h hemoglobin antibody that is coated on the test region. If hemoglobin is present of 30 ng/ml or greater, the result is the formation of a colored band in the test region. If there is no h Hemoglobin in the sample, the area will remain colorless. The sample continues to move to the control area where Goat anti-mouse IgG antibody will capture gold-sample antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

PACKAGE CONTENT

☐ Pouch content: Cassette with desiccant.
☐ Test instruction
☐ Stool Extraction Buffer Vails (25 Nos.)

PRECAUTIONS

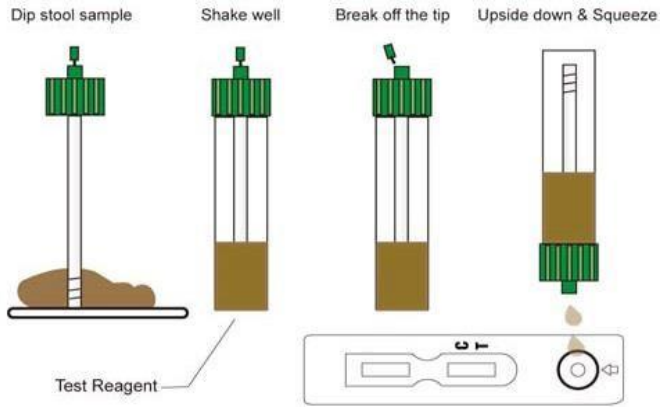
☐ For *in vitro* diagnostic use only.
☐ Do not reuse.
☐ Test device should remain sealed until use.
☐ Do not use after the expiration date printed on the pouch.
- Keep out of children's reach.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.

☐ The test device should be kept away from direct sunlight, moisture and heat.

TEST PROCEDURES



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 and 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 3 days at room temperature (15-30°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 3 full drops of the extracted specimen (approx. 120µL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration above.

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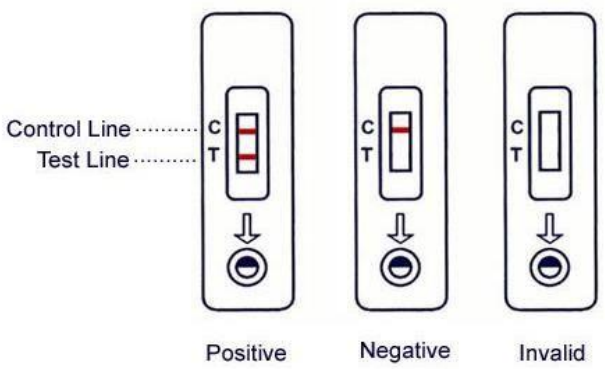
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5. Wait for the colored line(s) to appear. Read results in 5-20 minutes. Do not interpret the result after 30 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

INTERPRETATION OF THE RESULTS



Negative
Distinct pink color bands appear at the control and test line regions.

Positive
Only one pink color band appears on the control region. There is no apparent color band on the test region.

Invalid
No visible band at control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

PERFORMANCE CHARACTERISTICS

Sensitivity:
The analytical sensitivity of the test is 30 ng/ml hemoglobin or 6 µg hemoglobin/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. Samples containing the following substances both positive and negative control with no effect on the test results.

SUBSTANCES CONCENTRATIONS

▪ Beef Hemoglobin	1 mg/ml
▪ Chicken Hemoglobin	1 mg/ml
▪ Goat hemoglobin	1 mg/ml
▪ Pork hemoglobin	1 mg/ml
▪ Rabbit hemoglobin	1 mg/ml
▪ Horseradish peroxidase hemoglobin	1 mg/ml

Interference testing:
The following substances were added to h Hemoglobin free and 50 ng/ml controls. No interference was found with any of the substances at the following concentrations:

▪ Acetaminophen	20 mg/dl
▪ Acetylsalicyclic Acid	20 mg/dl
▪ Ampiclin	40 mg/dl
▪ Ascorbic Acid	40 mg/dl
▪ Atropine	40 mg/dl
▪ Caffeine	40 mg/dl
▪ Gentisic acid	40 mg/dl
▪ Glucose	2000 mg/dl
▪ Human Albumin	2000mg/dl
▪ Urea	4000 mg/dl
▪ Uric Acid	10 mg/dl

LIMITATIONS

☐ This product is designed for in vitro diagnostic use only.
☐ There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond The control of the manufacturer, such as technical or procedural errors associated with the testing.
☐ As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

CONTACT INFORMATION

CE

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Protect from light and moisture		Do not reuse

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- Horse hemoglobin 1 mg/ml

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