Fecal occult blood cassette CE

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For professional *in vitro* diagnostic use only			

FECAL OCCULT BLOOD

A rapid one test for the qualitative detection of human occult blood in feces.

ONE STEP

PRINCIPLE

The LINEAR Fecal Occult Blood cassette 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.

REAGENT COMPOSITION

FOB test device, contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane.

PACKAGING CONTENTS

REF 4325225 25 FOB test device
25 Specimen collection tubes with extraction buffer

PRECAUTIONS

- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the foil 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.

SPECIMEN COLLECTION AND 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.

STORAGE AND STABILITY

Store at 2-30ºC.
The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

MATERIAL REQUIRED

- Timer.
- Specimen collection container.

PROCEDURE

Allow test device, 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:

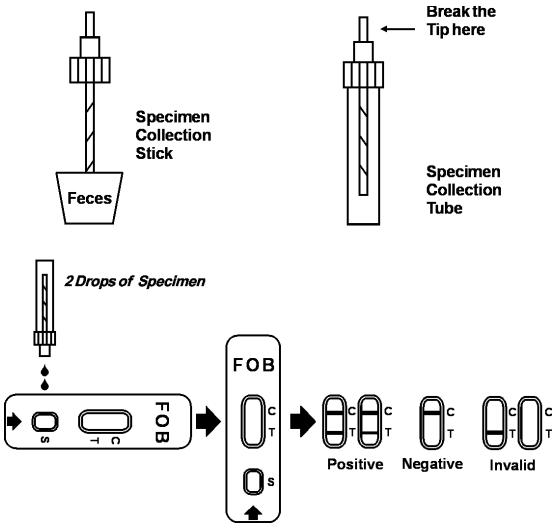
   Unscrew the cap of the specimen collection tube and then randomly **stab the specimen collection stick into the fecal specimen in at least 3 different sites**. Do not scoop the fecal specimen.

   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 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 2-3 full drops of the extracted specimen** (approx. 90 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.

5. Wait for the red line(s) to appear. **Read results at 5 minutes**. Do not interpret the result after 10 minutes.



QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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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 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 red line appears in the control region (C). No apparent colored 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 device. 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.
The Controls are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

CLINICAL SIGNIFICANCE

Many diseases can cause hidden blood in the feces. This is also known as Fecal 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-restriction prior to the testing.
The LINEAR Fecal Occult Blood is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses double antibody sandwich assay to selectively detect Fecal Occult Blood at 40 ng/mL or higher. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

ANALYTICAL PERFORMANCE

Accuracy

The LINEAR Fecal Occult Blood cassette has be compared with another leading commercial rapid test using clinical specimens.

Method		**Other Rapid Test**		**Total Results**
LINEAR Fecal Occult Blood	Results	Positive	Negative	
	Positive	325	9	334
	Negative	16	1024	1040
Total Results		341	1033	1374

Relative Sensitivity: 95.3% (92.5%-97.3%)
Relative Specificity: 99.1% (98.4%-99.6%)
Relative Accuracy: 98.2% (97.3%-98.8%) *95% Confidence Intervals

Sensitivity

The LINEAR Fecal Occult Blood cassette can detect levels of Fecal Occult Blood as low as 40 ng/mL.

Hook or Prozone effect

Specimens containing as much as 0.5 mg/mL hemoglobin can still test positive. Tests do not show a hook or prozone Effect up to maximum observed physiological concentrations (0.5 mg/mL).
Thus, the working range of the LINEAR Fecal Occult Blood cassette is from 40 ng/mL to 0.5 mg/mL.

Specificity

LINEAR Fecal Occult Blood cassette is specific to human hemoglobin. Specimen containing the following substances were diluted in the extraction buffer to a concentration of 0.5 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.

NOTES

1. LINEAR Fecal Occult Blood cassette will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding. Other than colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritation.
2. 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.
3. Urine and excessive dilution of specimens with toilet water may cause erroneous test results.
4. This test may be exhibit decreased sensitivity for upper gastrointestinal bleeding, as blood degrades as it passes through the gastrointestinal tract.
5. Not all colorectal bleeding is due to precancerous or cancerous polyps. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
7. Other clinically available tests are required if questionable results are obtained.

CLINICAL SPECIFICITY

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

1. Iron. Food supplements with iron increase the release of blood in the colon. Iron itself does not cross-reacting with the test.
2. Acetylsalicylic acid is the primary compound in many headache drugs (e.g. Aspirin® from Bayer), and is sometimes used as a substitute for macumar as a blood diluter. Very small amounts of blood are generally present in fecal samples in healthy humans. This is far below the sensitivity of the test and is unrelated to cancer. Patients taking blood diluters may experience more intense bleeding and experience false positive results.
3. Coumarins (e.g. Macumar®) are used as drugs for the prevention of heart attacks, and against thrombosis and stroke. Similar to ASA, coumarins are blood diluters. Very small amounts of blood are nearly always present in the fecal samples of healthy humans. This is far below the sensitivity of the test and is unrelated to cancer. Patients taking blood diluters may experience more intense bleeding and experience false positive results.
4. Hemorrhoids. Patients with hemorrhoids may suffer from bleeding. Therefore, fecal specimens may be contaminated with blood unrelated to cancer.
5. Monthly period. Small amounts of blood released during a 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. To avoid detection of urine-related blood, stool specimens should not come into contact with urine.

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