Fecal occult blood cassette

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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

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, 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. Specimen 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 3 drops of the extracted specimen (approx. 120 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 8 minutes.

PRINCIPLE

The LINEAR Fecal Occult Blood is a qualitative, membrane based sandwich immunoassay that has been designed for the detection of human hemoglobin in stool specimen through visual interpretation of color development in the test device.

In this assay fecal occult blood (FOB) is detected with the aid of specific antibodies against hemoglobin. After the addition of the sample (feces diluted in buffer) a color-labelled antibody specifically binds to hemoglobin if it is present in the sample. When this complex migrates upward on the membrane by capillary action, it is captured with the aid of another specific antibody at the test result line region of the test. A red test result line is generated. If no hemoglobin is present the color labelled antibody cannot bind at the test result line region. No red test result line is formed. So the presence of a colored test result line 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.

REAGENT COMPOSITION

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

PACKAGING CONTENTS

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<td>25 Specimen collection tubes with extraction buffer</td>
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Warning: The buffer contain sodium azide. Do not allow to contact with skin or mucous membranes.

STORAGE AND STABILITY

Store at 2-30°C. 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.

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.

MATERIAL REQUIRED

- Timer.
- Specimen collection container.

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 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. Comparison of the line intensities is not recommended.

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. Control standards 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.

Note: When testing control material dissolved in buffer the background of the assay is usually clear within 5 minutes. However, when fecal samples are tested, the background may appear slightly yellowish due to the original color of the fecal samples. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.

CLINICAL SIGNIFICANCE
Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood, 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-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 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.

ANALYTICAL PERFORMANCE
A. Analytical Sensitivity
A sample containing human hemoglobin at concentration equal to 2 µg Hemoglobin/g feces (resp. 40 ng Hemoglobin/mL buffer after extraction) produces a positive result. In some cases sample containing human hemoglobin at concentrations less than 2 µg/g feces can also be tested as positive.

Hook or Prozone effect
Sample containing as high as 1,250 µg hemoglobin/g feces (resp. 40 ng Hemoglobin/mL buffer after extraction) produces a positive result. In some cases sample containing human hemoglobin at concentrations less than 2 µg/g feces can also be tested as positive.

B. Analytical Specificity
Linear FOB Test is specific for human hemoglobin and does not show any cross-reaction with the hemoglobin from bovine, pig, horse and sheep up to concentrations of 0.5 mg/mL. Hemoglobin from rabbit and polecats may cause cross reactions. Linear FOB Test does not show any cross reaction with billirubin, vitamin C and horse radish peroxidase.

C. Clinical Specificity
The following non-cancer related factors may cause blood in feces samples:

1. Iron. Food supplementation with iron leads to increased release of blood in the colon. Iron itself is not cross-reacting with the test.
2. Acetylsalicylic acid. ASA is main compound in a lot of drugs against headache, and is sometimes used to substitute macumar as a blood diluter. Almost always there are very small amounts of blood in fecal samples in case of healthy humans. This is far below the sensitivity of our test and has nothing to do with cancer or any other serious matter. However, if a patient takes blood diluters bleeding can be more intensive. Therefore the cut-off of Linear FOB test may be reached.
3. Courmarin. Used as drugs (e.g. Macumar®) for prevention of heart attacks, against thrombosis and stroke. Similar to ASA, cumarines are blood diluters. Almost always there are very small amounts of blood in fecal samples in case of healthy humans. This is far below the sensitivity of Linear FOB test and has nothing to do with cancer or any other serious matter. However, if a patient takes blood diluters, bleeding can be more intensive. Therefore the cut-off of Linear FOB test may be reached.
4. Hemorrhoids. Therefore fecal sample may be contaminated with blood which is not associated with cancer.
5. Monthly period. Small amounts of blood released because of 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 samples. To avoid detection of urine-related blood, stool sample should not get in contact with urine.

PRECAUTIONS
- Do not mix sample collection tubes from different lots.
- Do not touch or spill liquid onto the white membrane in the test result window.
- Avoid cross-contamination of samples by using a new specimen collection container and new specimen collection tube.
- All patient’s samples should be treated as if capable of transmitting disease. Adequate handling and disposal methods should be established. It is recommended to wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being handled. Do not eat, drink or smoke in the area where specimens or kits are handled.
- Ensure that patients closely follow the specimen collection procedures.

NOTES
1. LINEAR Fecal Occult Blood will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
2. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
3. Other clinically available tests are required if questionable results are obtained.

REFERENCES