

A TEST FOR FECAL OCCULT BLOOD

Cat. No. 23 038031, 23 038032



INTENDED USE

This product is a guaiac slide test for the qualitative detection of fecal occult blood. It is a useful aid in the diagnosis of a number of gastrointestinal disorders and is recommended for use in:

1. Routine physical examinations
2. Routine hospital testing
3. Mass screening for colorectal cancer

SUMMARY AND EXPLANATION

The detection of occult blood is critical for the diagnosis of many gastrointestinal diseases. The presence of occult blood in fecal material may indicate gastrointestinal pathology such as hemorrhoids, diverticulitis, fissures, colitis or colorectal cancer. Fortunately, these conditions may be detected with several diagnostic methodologies available including testing of stools for occult blood, complete physical examination with digital examination, and proctosigmoidoscopy. Air contrast barium enema and fiberoptic colonoscopy also contribute significantly to the diagnosis of colonic problems. Unfortunately, only a small percentage of bowel and rectal cancers are found on digital examination and patients with no symptoms of bowel disease do not readily present themselves for procedures such as proctosigmoidoscopy and barium enema.

This test is a simple, aesthetic, inexpensive test designed for use in the collection and preparation of stool specimens. It overcomes the instability of guaiac solution and the hypersensitivity of benzidine and ortho-tolidine.¹⁰

If a positive result is obtained with the test, a follow-up with additional diagnostic tests, as soon as possible, is essential.

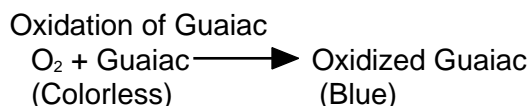
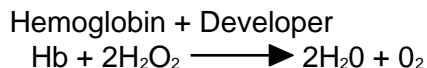
As with any occult blood test, results cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. This test is not intended as a replacement for other diagnostic procedures such as proctosigmoidoscopy examination, barium enema, and X-ray studies.

PRINCIPLE

The test is composed of guaiac impregnated paper enclosed in a cardboard frame which permits sample application to one side with development and interpretation on the reverse side. The process involves placing two specimens, collected from three successive evacuations, onto the guaiac paper.

Like all guaiac paper tests for occult blood, it is based on the oxidation of phenolic compounds present in the guaiac (i.e. guaiaconic acids) to quinones resulting in production of the blue color.¹ Because of its similarity to the prosthetic group of peroxidase, the heme portion of the hemoglobin molecule can function in a pseudoenzymatic manner, catalyzing the oxidation of guaiac.

When a fecal specimen containing occult blood is applied to the test paper, contact is made between hemoglobin and the guaiac. A pseudoperoxidase reaction will occur upon the addition of the developer solution, with a blue chromagen formed proportional to the concentration of hemoglobins. The color reaction will occur after thirty seconds.



The kits include Positive/Negative Monitors which provide a quality control system for each test. The Monitors are incorporated into each slide.

REAGENTS

1. Fecal Occult Blood Slides and Monitors

Reactive Ingredients: The slides are made of quality-controlled paper impregnated with guaiac resin. The Positive Monitor contains an impregnated substance which will turn blue if product is functioning properly. The Negative Monitor consists of guaiac impregnated paper.

WARNING: FOR IN-VITRO DIAGNOSTIC USE ONLY.

Preparation for Use: The slide is ready for use as packaged.

Storage and Stability: This product should be stored at room temperature (15-30°C) and is stable until the expiration date indicated on the box. Do not use after the expiration date. Slides should be protected from heat, sunlight, humidity, fluorescent light, U.V. radiation, excessive air flow, or volatile chemicals (e.g. iodine or bleach). Do not refrigerate or freeze.

Signs of Deterioration: Discoloration of the normally light tan paper may occur if exposed to sunlight, fluorescent or ultraviolet light. Failure of the control system to react as expected may be

indicative of deterioration of the developer or the slide, and test results should be regarded as invalid.

2. Fecal Occult Blood Developer

Reactive Ingredients: The Developer contains < 6% hydrogen peroxide and denatured alcohol.

WARNING: FOR IN-VITRO DIAGNOSTIC USE ONLY. DANGER: FLAMMABLE. NEVER PIPETTE BY MOUTH. VAPOR HARMFUL. DO NOT INGEST OR PLACE IN EYES. May be fatal or cause blindness if swallowed. Keep away from heat, sparks or open flame. Avoid contact with eyes or skin. Should contact occur, flush the affected area with water and get immediate medical attention.

Preparation for Use: The Developer is ready for use as packaged.

Storage and Stability: Fecal Occult Blood Developer should be stored tightly capped at 15 to 30°C protected from heat. Under these conditions the developer will remain stable until the expiration date indicated on the bottle. Do not use after the expiration date. Do not substitute reagents from other manufacturers.

Signs of Deterioration: Failure of the Positive/Negative Monitors to react as expected may be indicative of deterioration of the developer or the slide and the test results should be regarded as invalid.

SPECIMEN COLLECTION AND HANDLING

Patient Preparation:

A. It is recommended that the patient be placed on a high residue diet starting 2 days prior to and continuing through the test period.

DIET MAY INCLUDE:

1. Meats: Only small amounts of well-cooked chicken, turkey and tuna.
2. Vegetables: Generous amounts of both raw and cooked vegetables including lettuce, corn, spinach, carrots and celery. Avoid raw vegetables with high peroxidase activity such as those listed below.
3. Fruits: Plenty of fruits, especially prunes and apples.
4. Cereals: Bran and bran-containing cereals.
5. Moderate amounts of peanuts and popcorn daily. If any of the above foods are known to cause discomfort, the patient is instructed to consult his/her physician.

TO BE AVOIDED:

1. Meat: Diet should not include any red or rare meat.
2. Raw fruits and vegetables containing high peroxidase activity:

Turnip	Cauliflower	Red radishes
Broccoli	Cantaloupe	
Horseradish	Parsnip	

B. Alternately, the special diet may be omitted initially with dietary restrictions imposed upon the retesting of all positive results. However, because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, all patients with positive tests regardless of diet, should have follow-up diagnostic procedures done.

C. Other factors which affect the test:

1. Medications: For 7 days prior to and during the testing, do not ingest aspirin⁹ or other anti-inflammatory medicines. For 2 days prior to and during testing, do not use rectal medicines, tonics or vitamin preparations which contain Vitamin C (ascorbic acid) in excess of 250 mg per day.
2. Bleeding hemorrhoids or open cuts on hands.
3. Collection of specimen during menstrual period.
4. Improper specimen collection.
5. Other diseases of the gastrointestinal tract such as colitis, gastritis, diverticulitis and bleeding ulcers.

Specimen Handling: Using the applicators provided, obtain a small sample of the stool from the toilet bowl. It is very important that the stool specimen be applied as a **very thin smear** to the slides. Obtain a second sample of the stool, from a different location, in the same manner. Apply a **very thin smear** to the slide. Allow the smears to air dry. The smears may be prepared and developed immediately or prepared and stored up to 12 days prior to development. Care should be taken so that anything coming into contact with the specimen is free of blood. Because of the non-homogeneity of the stool, it is recommended that the test be performed on three (3) consecutive evacuations or ones as close together as possible.^{2,3}

Patient specimens and all materials in contact with them should be handled as potentially infectious and should be disposed of using proper precautions.

Return the completed slide to your physician or laboratory as instructed. If the slide is returned by mail, use the foil-back envelope provided. DO NOT use a standard paper envelope as they are not approved by U.S. Postal Regulations.

Interfering Substances: Ingestion of ascorbic acid (Vitamin C) in high doses has been shown to cause false negative results, and intake should be discontinued 2 days prior to and during the test period.⁴

Peroxidase from fruit and vegetables can cause false positive results.⁵⁻⁸ Elimination of red meat from the diet during the test period eliminates the source of hemoglobin which can cause false positives. Oral medications (such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroids, etc.) and heavy alcohol consumption may cause irritation or bleeding of the gastrointestinal tract and should be discontinued for 7 days prior to and during the test period.

PROCEDURE

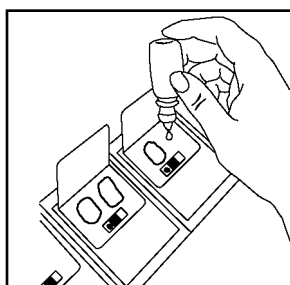
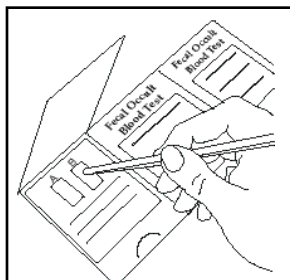
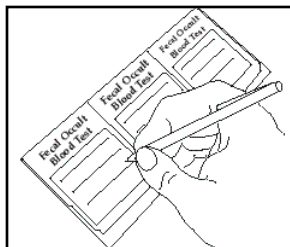
Materials Provided: The following materials are provided for the performance of fecal occult blood tests:

- Fecal Occult Blood Slides with Monitors
- Fecal Occult Blood Developer
- Specimen Applicators
- Collection Tissues
- Mailing Envelopes

METHOD

Fecal Occult Blood Slide

1. Remove all cleaners or deodorizers from the toilet bowl and tank. Flush the toilet twice to remove chemicals that may be present. If a noticeable color exists, flush until it disappears.
2. Supply all information requested on the front flap of the slide.
3. Open the front flap.
4. If provided, unfold one of the collection tissues. Float it on the water so that the edges stick to the sides of the bowl. The stool should fall onto the tissue. If the packet does not contain tissues, the stool should fall into the water.
5. Using the applicator provided, collect a small stool specimen from the toilet, on one end of the applicator. Apply a **very thin smear** in Box A.
6. Reuse applicator to obtain a second sample from a different part of the stool specimen. Apply a **very thin smear** inside Box B. (On subsequent bowel movements, repeat above steps on additional slides.)
7. Allow the specimen to air dry, then close the cover.
8. Open perforated window on the back of the slide.
9. Apply two (2) drops of Fecal Occult Blood Developer to the back side of boxes A and B.

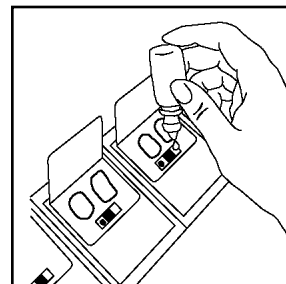


10. Read results after 30 seconds and within 2 minutes.
11. Record the results; any trace of blue color, within or on the outer rim of the specimen, is positive for occult blood.

Positive/Negative Monitors

Note: The procedure for developing the sample test must be completed, interpreted and recorded before proceeding with the development of Monitors.

1. To develop Monitors, place one or two drops of Fecal Occult Blood Developer between the Positive and Negative Monitor boxes.
2. Read the results after 30 seconds and within 2 minutes.
3. Positive Monitor should turn blue, but the Negative Monitor should not have any trace of blue.



Stability of End Product: The color reaction is not permanent. Fading may occur after approximately 2 minutes.

QUALITY CONTROL

Positive/Negative Monitors are provided on each Slide. This specially treated area provides assurance that the guaiac-impregnated paper and the Fecal Occult Blood Developer are reacting according to product specifications. The Positive Monitor is an impregnated substance in a base carrier and will turn blue, after 30 seconds and within 2 minutes, after the application of Fecal Occult Blood Developer if the test system is reacting according to product specifications. The Negative Monitor consists of guaiac impregnated paper and will not turn blue upon addition of Fecal Occult Blood Developer.

INTERPRETATION OF RESULTS

Any trace of blue color within the specimen application area, within the specified time, is positive for occult blood if the Positive/Negative Monitors react properly. An absence of blue color indicates no detectable occult blood in the specimen. Remember always to develop the test, interpret and record results before developing the Positive/Negative Monitors. Interpretation of the test should not be done by one who is color blind.

LIMITATIONS

Results obtained with this test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. False negative tests may be obtained since most bleeding occurs intermittently. Fecal Occult Blood tests are designed as a preliminary screen and are not intended to replace other diagnostic procedures

such as proctosigmoidoscopy, barium enema or X-ray studies. This method will detect only hemoglobin released upon hemolysis of the red cell. Should whole blood be applied to the test paper, it is necessary to hemolyze the red cells by the addition of a drop of water before adding the developer. Refer to "Interfering Substances" for a further list of limiting substances.

EXPECTED RESULTS

The guaiac paper tests detect occult blood, but they are not diagnostic for disease. Positive occult blood tests may be obtained for reasons which range from red meat in the diet, diverticulitis, hemorrhoids, colitis to colorectal cancer. Patients who have a positive test should immediately consult a physician who can perform definitive tests to determine the cause of bleeding. Patients experiencing symptoms such as persistent diarrhea or constipation, abdominal pain, visible bleeding, etc., should consult a physician.

This method will detect 10 mg of hemoglobin per gram of homogenized fecal material.¹⁴ Guaiac impregnated paper has been extensively studied.¹¹⁻¹³ Clinical studies demonstrate that the guaiac impregnated slide tests yield a positive result of 3-5% in screening programs. The false positive rate was between 1-2% during controlled conditions (diet, medical supervision, etc.).

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Manufactured for:



Houston, Texas