

ColoScreen®

A Test for Occult Blood

Helena  Laboratories

INTENDED USE

ColoScreen 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

The detection of occult blood is critical to 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 can be detected with several diagnostic methodologies available which include 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 lesions. 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.

The American Cancer Society recommends annual fecal occult blood test plus flexible sigmoidoscopy every 5 years for both men and women beginning at age 50.¹ A colonoscopy is suggested every 10 years. Colorectal cancer screening should begin earlier and should be done more often if you have increased risk factors such as personal or family history of colorectal disease.¹

ColoScreen 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.²

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

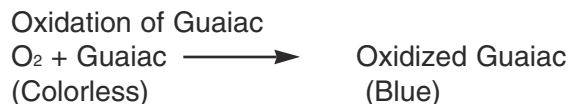
PRINCIPLE

ColoScreen is composed of guaiac impregnated paper enclosed in a cardboard frame which permits sample application to one side, and development and

interpretation on the reverse side. The process involves placing two specimens, collected from each of three successive evacuations, onto the guaiac paper.

ColoScreen, like all guaiac paper tests for occult blood, 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.³ 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 ColoScreen kits include ColoCheck Monitors which provide a quality control system for each test. The ColoCheck Monitors are incorporated into each slide.

REAGENTS

1. ColoScreen Slides and Monitors

ColoScreen Tape and Monitors

Ingredients: ColoScreen Slides and ColoScreen Tape are made of quality controlled paper impregnated with guaiac resin. ColoCheck Positive Monitor contains an impregnated substance which will turn blue if product is functioning properly. The ColoCheck Negative Monitor consists of guaiac impregnated paper.

WARNING: FOR IN-VITRO DIAGNOSTIC USE.

Preparation for Use: The slide and tape are ready for use as packaged.

Storage and Stability: These products should be stored at room temperature (15 to 30°C) and are stable until the expiration date indicated on each slide and tape box. Do not use after expiration date. Both items should be protected from heat, humidity, light, 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/tape, and test results should be regarded as invalid.

2. ColoScreen Developer

Ingredients: ColoScreen Developer contains < 6% hydrogen peroxide and denaturated ethanol.

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

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

Storage and Stability: ColoScreen Developer should be stored tightly capped at 15 to 30°C protected from heat and light. 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 ColoCheck Monitors to react as expected may be indicative of deterioration of the developer or the slide/tape, 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 before 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 re-testing 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 aspirin⁴ or other anti-inflammatory medicines. For 2 days prior to and during testing, do not use rectal medicines, or 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 cycle.
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 ColoScreen Slides and Tape. 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 slide smears may be prepared and developed immediately or 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 nonhomogeneity of the stool, it is recommended that the test be performed on three (3) consecutive evacuations, or as close together as possible.^{5,6}

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.⁷ Peroxidase from fruit and vegetables can cause false positive results.⁸⁻¹¹ 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, phenalbutazone, 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 by Helena Laboratories for performance of fecal occult blood tests:

- ColoScreen Slides with Monitors
- ColoScreen Tape with Monitors
- ColoScreen Developer

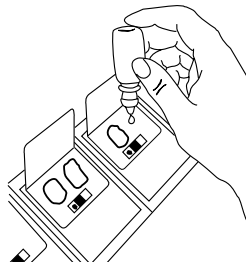
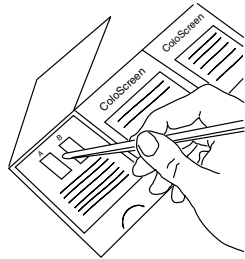
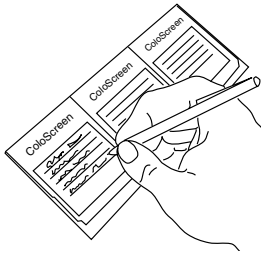
Specimen Applicators ColoScreen Mailing Envelopes

Kit combinations have been designed to meet individual laboratory demands. Please see the back page of this package insert for kit listings.

METHOD

A. ColoScreen Slide

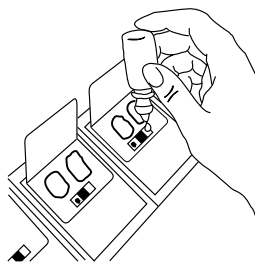
1. Supply all information listed on the front flap of the ColoScreen Slide.
2. Open the front flap.
3. Using the applicator provided, collect a small amount of stool specimen from the toilet, on one end of applicator. Apply a **very thin smear** in Box A.
4. Reuse applicator to obtain a second sample 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.)
5. Allow the specimen to air dry, then close the cover.
6. Open perforated window on the back of the slide.
7. Apply two (2) drops of ColoScreen Developer to the back side of boxes A and B.
8. Read results after 30 seconds and within 2 minutes.
9. Record the results; any trace of blue color, within or on the outer rim of the specimen, is positive for occult blood.



ColoCheck Monitors

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

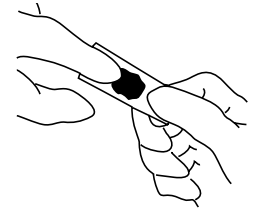
1. To develop ColoCheck Monitors, place one or two drops of ColoScreen Developer between the Positive and Negative Monitor boxes.
2. Read the results after 30 seconds and within 2 minutes.
3. Positive ColoCheck Monitor should turn blue, but the Negative ColoCheck Monitor should not have any trace of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



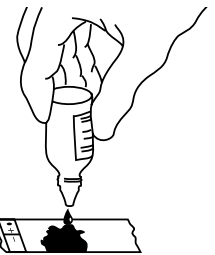
B. ColoScreen Tape

1. Tear a segment of tape from the dispenser. Note that Positive and Negative Monitors are printed on one side of the paper segment.

2. Apply a **very thin smear** of fecal material to the tape on the side opposite the Monitors. Do not smear the specimen over the area where the Monitors are printed.



3. Turn the tape segment over and apply two (2) drops of ColoScreen Developer to the back side of the application area.



4. Read results after 30 seconds and within 2 minutes.

5. Any trace of blue color within the smear is positive for occult blood.

6. To develop the Monitors, follow the instructions given in the "ColoCheck Monitor" section above.

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

QUALITY CONTROL

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

INTERPRETATION OF RESULTS

Any trace of blue color within the specimen application area is a positive for occult blood, if ColoCheck Monitors react properly. Remember always to develop the test, interpret, and record results before developing the ColoCheck Monitors. Interpretation of the test should not be done by one who is color blind.

LIMITATIONS

Results obtained with ColoScreen cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. False negative results may be obtained, since most bleeding occurs intermittently. ColoScreen 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. ColoScreen 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 verify that they have followed a proper diet prior to specimen collection, and should immediately consult a physician who can perform definitive tests to determine the cause of bleeding. Patients experiencing symptoms such as persistent diarrhea, constipation, abdominal pain, visible bleeding, etc., should consult a physician.

ColoScreen will detect 10 mg of hemoglobin per gram of homogenized fecal material.¹² Guaiac impregnated paper has been extensively studied.¹³⁻¹⁵ Clinical studies illustrate that the guaiac impregnated slide tests yield a positive testing range 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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PRODUCTS AVAILABLE

	Cat. No.
ColoScreen III Office Pack	5071
Includes: 100 ColoScreen III Slides 6 x 15 mL ColoScreen Developer 300 Applicators 100 Mailing Envelopes	
ColoScreen Lab Pack	5072
Includes: 100 ColoScreen Single Slides 2 x 15 mL ColoScreen Developer 100 Applicators	
ColoScreen 1000 Pack	5076
Includes: 1000 ColoScreen Single Slides 20 x 15 mL ColoScreen Developer 1000 Applicators	
ColoScreen Developer	5077
20 x 15 mL vials	
ColoScreen Developer-2	5078
50 x 2 mL vials	
ColoScreen Tape	5079
Includes: 2 ColoScreen Tape Dispensers each containing a 100 test roll of guaiac paper and 2 x 15 mL ColoScreen Developer	
ColoScreen III Lab Pack	5082
Includes: 35 ColoScreen III Slides 2 x 15 mL ColoScreen Developer 100 Applicators	
ColoScreen III 1000 Pack	5083
Includes: 350 ColoScreen III Slides 20 x 15 mL ColoScreen Developer 1000 Applicators	
100 ColoScreen III Envelopes	1002

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