BIBLIOGRAPHY


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 for the detection 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 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.

ColoScreen is a simple, aesthetic, inexpensive test designed for use in the collection and preparation of stool specimens. It offers the instability of guaiac solution and the hypersensitivity of benzidine and orthotolidine.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 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.1 Because of its similarity to the prosthetic group of peroxidase, the hematin 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 the guaiac paper and the guaiac. A pseudoperoxidase reaction will occur upon the addition of the developer solution, with a blue chromagen formed proportionally to the concentration of hemoglobin. The color reaction will occur after thirty seconds.

Helena + Developer
Hb + 2H₂O₂ → 2H₂O + O₂
Oxidation of Guaiac
O₂ + Guaiac → Oxidized Guaiac (Colorless) (Blue)

The ColoScreen kit includes 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
Reactive Ingredients: ColoScreen Slides 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 is 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. 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, and test results should be regarded as invalid.

2. ColoScreen Developer
Reactive Ingredients: ColoScreen Developer contains < 6% hydrogen peroxide and denatured ethanol.

WARNING: FOR IN-VITRO DIAGNOSTIC USE. DANGER: FLAMMABLE. NEVER PIPEETE BY MOUTH. VAPOR HARMFUL. DO NOT INGEST OR...
**METHOD**

Supply all information listed on the front flap of the ColoScreen Slide. Open the front flap.

A. Sample Collection and Application

1. Unfold one collection of tissues. Float it on the surface of the stool. Any blue that the edges stick to the sides of the toilet bowl. The stool should fall onto the tissue.
2. Using the applicator provided, collect a very thin smear of the specimen from different parts of the stool (surface or interior) of the stool on one end of applicator. Apply a very thin smear in Box A.
3. 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.)
4. Flush tissue with stool, and discard stick in waste container.
5. Allow the smear to air dry, then close the cover.

B. Development

1. Perforate window on the back of the slide.
2. Apply two (2) drops of ColoScreen Developer to the back side of boxes A and B.
3. Read results after 30 seconds and within 2 minutes.
4. Record the results; any trace of blue color, within or on the outer rim of the specimen, indicates positive for occult blood.

**QUALITY CONTROL**

ColoScreen Checks are provided on each ColoScreen Slide. This control 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 not negated, but the cells burst, 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. A 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 or constipation, abdominal pain, visible bleeding, etc., should consult a physician.

ColoScreen will detect 10 mg of hemoglobin per gram of homogenized fecal material.4 Guaiac impregnated paper has been extensively studied.5,6 Clinical studies illustrate that the guaiac impregnated slide tests yield a positive diagnostic rate of 3-5% in screening programs. The false positive rate was between 1-2% during controlled conditions (diet, medical supervision, etc.).
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. If contact should 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, 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 cranberries.
5. Moderate amounts of peanuts and popcorn.

B. Other factors which affect the test:
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.
3. Positive ColoCheck

METHOD

Supply all information listed on the front flap of the ColoScreen Slide. Open the front flap.

A. Sample Collection and Application

1. Unfold one of the collection tissues. Float it on the surface of the developer so that the edges stick to the sides of the toilet bowl. The stool should fall onto the tissue.
2. Using the applicator provided, collect a small amount of specimen from different areas (e.g. surface or interior) of the stool on one end of applicator. Apply a very thin smear in Box A.
3. 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.)
4. Flush tissue with stool, and discard stick in waste container.
5. Allow the specimen to air dry, then close the cover.

B. Development

1. Open perforated window on the back of the slide.
2. Apply two (2) drops of ColoScreen Developer to the back side of boxes A and B.
3. Read results after 30 seconds and within 2 minutes.
4. Record the results; any trace of blue color, within or on the outer rim of the specimen area is a positive for occult blood.

C. 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.

Stabilized 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. The test system 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 area is a positive 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

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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. A positive test result should verify that the patient has 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 or constipation, abdominal pain, visible bleeding, etc., should consult a physician.

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The detection of occult blood is critical for the detection 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 can be detected with the 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.

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-phenylenediamine.

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 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 and barium enema.

For Sales, Technical and Order Information and Service Assistance, call 800-231-5663 toll free.

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