COLOSCREEN-ES
A TEST FOR OCCULT BLOOD

Cat. No. 5085

Helena Laboratories

INTENDED USE

ColoScreen-ES (Extra Sensitive) 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 gastro-intestinal 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.

ColoScreen-ES is a simple, aesthetic, inexpensive test designed for collection and preparation of stool specimens.

ColoScreen-ES is an improvement over the traditional gum guaiac methods. It overcomes the instability of guaiac solution and the hypersensitivity of benzidine and ortho-tolidine.[1] It offers increased sensitivity for the detection of blood in the stool. The increased sensitivity can be noted in the improved readibility of the test because the color development is more intense and stable.

As a consequence of this increased sensitivity, the test will also have a higher rate of false positives among patients. The recommended diet must be followed to minimize false positive results.

Results of the traditional guaiac-based products indicates that results are positive in only 50 to 65 percent of patients with colorectal cancer and 25 to 35 percent of patients with polyps.[2] The ColoScreen-ES test offers the increased sensitivity that is desired by medical professionals.

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 procto-sigmoidoscopy examination, barium enema, and X-ray studies.

PRINCIPLE

ColoScreen-ES 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 onto the guaiac paper which have been collected from each of three successive evacuations.

ColoScreen-ES, 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 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 hemoglobin 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 hemoglobins. The color reaction will occur after thirty seconds.

Hemoglobin + Developer

$$Hb + 2H_2O_2 \longrightarrow 2H_2O + O_2$$

Oxidation of Guaiac

$$O_2 + \text{Guaiac} \longrightarrow \text{Oxidized Guaiac}$$

(Colorless) (Blue)

The ColoScreen-ES kits include ColoCheck Monitors which provide a quality control system for each test. The ColoCheck Monitors are incorporated into each slide.

REAGENTS

1. ColoScreen-ES Slides and Monitors

Reactive Ingredients: ColoScreen-ES 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-ES Developer

Reactive Ingredients: ColoScreen-ES Developer contains < 6% hydrogen peroxide in propanol.

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-ES Developer is ready for use as packaged.

Storage and Stability: ColoScreen-ES 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 under “To Be Avoided:”.
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 aspirin[4] 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 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-ES 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 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 ones 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 positive results. 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:

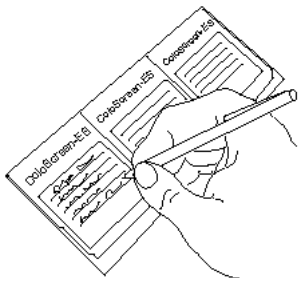
ColoScreen-ES Slides with Monitors
ColoScreen-ES Developer
Specimen Applicators
Collection Tissues
ColoScreen Mailing Envelopes

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

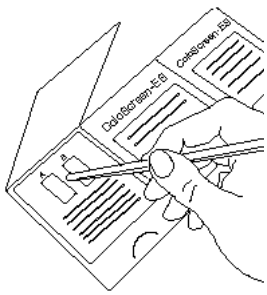
METHOD

ColoScreen Slide

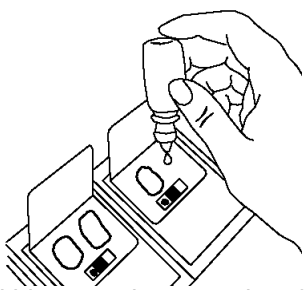
1. Supply all information listed on the front flap of the ColoScreen-ES Slide.
2. Open the front flap.
3. If provided, unfold one of the collection tissues. Float it on the surface of the water so that the edges stick to the sides of the toilet bowl. The stool should fall onto the tissue. If the packet does not contain tissues, the stool should fall into the water.



4. Using the applicator sticks provided, collect a small sample from the different areas of the stool. Apply a **very thin smear** in Box A.



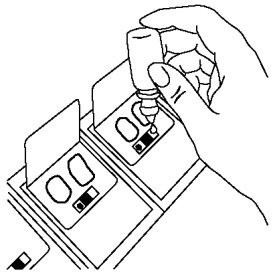
5. Reuse applicator to obtain a second sample from a different part of the stool specimen. Apply a **very thin smear** inside Box B. (On subsequent bowel movements, repeat above steps on additional slides.) Flush tissue with stool, and discard stick in waste container.
6. Allow the specimen to air dry, then close the cover.
7. To develop, open perforated window on the back of the slide.
8. Apply two (2) drops of ColoScreen-ES Developer to the back side of boxes A and B.
9. Read results after 30 seconds and within 2 minutes.
10. 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-ES 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.



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-ES Slide. This specially treated area provides assurance that the guaiac-impregnated paper and the ColoScreen-ES 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-ES 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-ES 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-ES 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-ES 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-ES will detect only hemoglobin released upon hemolysis of the red blood 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 to the sample 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 or constipation, abdominal pain, visible bleeding, etc., should consult a physician.

PERFORMANCE CHARACTERISTICS

Sensitivity

A sensitivity study was done using a whole blood sample, with a known hemoglobin concentration, and a stool sample which tested negative by a traditional guaiac method. The stool was titrated with aliquots of whole blood to produce various concentrations. Each concentration of stool was then applied to the slide and developed. Based on this study, ColoScreen-ES will give positive results 50-90% of the time at a level of 0.3 mg of hemoglobin per gram of stool.

Positivity

A study was done using asymptomatic persons, over the age of forty, who were instructed to follow the recommended diet. Data from this study indicated a positivity rate of 9% using ColoScreen-ES and 10% using Hemoccult Sensa.

BIBLIOGRAPHY

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4. Grossman, M.I. et al., Fecal Occult Blood Loss Produced by Oral and Intravenous Administration of Various Salicylates, Gastroenterology, 40:383-388, 1961.
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11. Winawer, S.J. and Fleisher, M., Sensitivity and Specificity of the Fecal Occult Blood Test for Colorectal Neoplasia, Gastroenterology, 82:986-991, 1982.

PRODUCTS AVAILABLE

	Cat. No.
ColoScreen-ES Office Pack (Includes: ColoScreen-ES Slides, 80; Collection Tissues, 240; ColoScreen-ES Developer, 6 x 15 mL; Applicators, 240; Mailing Envelopes, 80)	**5085**
ColoScreen-ES Lab Pack (Includes: ColoScreen-ES Single Slides, 100; ColoScreen-ES Developer, 2 x 15 mL; Applicators, 100)	**5086**
ColoScreen-ES Developer, 20 x 15 mL vials	**5088**

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

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Test System Code: 25291
Analyte Code: 9191
Complexity: Waived