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


PRODUCTS AVAILABLE

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

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

Helena Laboratories warrants its products to meet our published specifications and to be free from defects in materials and workmanship; Helena laboratories is obligated to correct the defect at no additional charge if the defect is so corrected within the warranty period. In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages. Helena Laboratories’ liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price from defects in materials and workmanship. Helena’s liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price. For Sales, Technical and Order Information and Service Assistance, call 800-231-5663 toll free.

ColoScreen-ES tests 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 in 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 colonscopy 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 guaiac gumaic methods. It overcomes the instability of guaiac solution and the hypersensitivity of benzidine and ortho-iodidine. 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. 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 proctosigmoidoscopy 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. 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 chromogen formed proportionally to the concentration of hemoglobin. The color reaction will occur after thirty seconds.

Hemoglobin + Developer
Hb + 2H₂O₂ → HBO₂ + O₂
Oxidation of Guaiac
O₂ + Guaiac → 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.

**Patient Specimens and All Materials in Contact with Them**

- **For Use:** Coldo-Screen-ES Developer
- **Reactive Ingredients:** Coldo-Screen-ES Developer contains < 0.5% hydrogen peroxide in proprietary.

**METHOD**

**Preparation for Use:** Coldo-Screen-ES Developer is ready for use as packaged.

**Storage and Stability:** Coldo-Screen-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 ColdoCheck 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 during the test period.
- **B.** Alternatively, 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.

**Preparation for Use:** Coldo-Screen-ES Developer is ready for use as packaged.

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**Signs of Deterioration:** Failure of the ColdoCheck 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.
- **2.** Vegetables: Generous amounts of both raw and cooked vegetables including lettuce, corn, spinach, potatoes, 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.

**To Be Avoided:**

- **1.** Meat: Diet should not include any red or rare meat.
- **2.** Raw fruits and vegetables containing high peroxidase activity: Turmeric, Cauliflower, radishes, Broccoli, Mustard, Horseradish, Parsnip.

**METHOD**

**Preparation for Use:** Coldo-Screen-ES Developer is ready for use as packaged.

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- **2.** Vegetables: Generous amounts of both raw and cooked vegetables including lettuce, corn, spinach, potatoes, 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.

**To Be Avoided:**

- **1.** Meat: Diet should not include any red or rare meat.
- **2.** Raw fruits and vegetables containing high peroxidase activity: Turmeric, Cauliflower, radishes, Broccoli, Mustard, Horseradish, Parsnip.

**PROCEDURE**

**Materials Provided:** The following materials are provided by Helena Laboratories for performance of fecal occult blood tests:

- Coldo-Screen-ES Slides with Monitors
- Coldo-Screen-ES Developer
- Specimen Applicators
- ColoCheck Monitors
- ColoCheck Mailing Envelopes

**RESULT INTERPRETATION:**

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

**LIMITATIONS:**

- **Results obtained with Coldo-Screen-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. Coldo-Screen-ES tests are designed as a preliminary screening test intended to replace other diagnostic procedures such as proctosigmoidoscopy, barium enema or X-ray studies. Coldo-Screen-ES cannot exclude lesions that may be detected only on hemoglobin detected 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 the specific type of occult blood tests may be obtained for reasons which range from red meat in the diet, diverticulitis, hemorrhoids, colitis to colorectal..."
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.

**WARNING:** FOR IN-VITRO DIAGNOSTIC USE. DANGER: FLAMMABLE, NEVER PIPEETTE 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, 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.

**Specimen Collection and Handling:**

1. **Patient Preparation:**
   - Meats: Only small amounts of well-cooked meats such as chicken, turkey and tuna.
   - Vegetables: Generous amounts of both raw and cooked vegetables such as lettuce, corn, spinach, carrots and celery. Avoid raw vegetables with high peroxidase activity such as those listed under “To Be Avoided.”
   - Fruits: Plenty of fruits, especially prunes and pears.
   - Cereals: Bran and bran-containing cereals.
   - Moderate amounts of peanuts and popcorn daily.
   - If any of the above foods are known to cause digestive discomfort, the patient is instructed to consult his/her physician.

2. **Raw fruits and vegetables containing high peroxidase activity:**
   - Turnip
   - Cauliflower
   - Red radishes
   - Broccoli
   - Carrot group
   - Horseradish
   - Parsnip

3. **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 bowl. It is very important that the stool sample 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 **second 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 any 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.

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 excess of 250 mg per day. Ingestion of ascorbic acid (Vitamin C) in excess of 250 mg per day 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.

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**METHOD**

**ColoScreen Slide**

1. Supply all information 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 tissue, place the stool into a water container.
4. Using the applicator sticks provided, collect a small sample from the different areas of the stool.
5. Apply a very thin smear in Box A. Use the applicator to obtain a second sample from a different part of the coloCheck specimen. Apply a very thin smear inside Box B. (On subsequent bowel movements, repeat above steps on additional slides.) Float 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 Development** 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 slide, is positive for occult blood.

**ColoCheck Monitors**

**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
- ColoScreen Mailing Envelopes

Kit combinations have been designed to meet individual laboratory demands. Please see the back page of this diagnostic procedures done.

**EXPECTED RESULTS**

The guaiac paper tests detect occult blood but they are not diagnostic for the specific type of occult blood tests may be obtained for reasons which range from red meat in the diet, diverticulitis, hemorrhoids, colitis to colorectal

**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 within 30 seconds after development of ColoScreen-ES Developer.
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

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 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.

ColoScreen-ES is a simple, aesthetic, inexpensive test designed for collection and preparation of stool specimens. ColoScreen-ES is an improvement over the traditional guaiac gum methodologies. It overcomes the instability of guaiac solution and the hypersensitivity of benzidine and ortho-phenylene. It offers increased sensitivity for the detection of blood in the stool. The increased sensitivity can be noted in the improved readability 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. The ColoScreen-ES test offers the increased sensitivity that is desired by medical professionals.

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-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 acid) to quinones resulting in production of the blue color. 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.

The ColoScreen-ES Slides are

Reactive Ingredients:

Hemoglobin + Developer
Hb + 2O2 = HbO2 + O2

Oxidation of Guaiac
O2 + Guaiac = Oxidized Guaiac (Colorless)

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