

ColoCARE® Office Pack

Cat. No. 5651, 5656

Helena  Laboratories

ColoCARE® is intended for the qualitative assessment of fecal occult blood when used as a screening aid in the diagnosis of various gastrointestinal disorders.

SUMMARY

ColoCARE provides a method for determining the presence of fecal occult blood that can be performed and analyzed without removing the specimen from the toilet bowl. Elimination of handling the stool specimen dismisses many of the patient's objections to self administering such a test. Increased patient acceptance results in wider use of the test, leading to earlier diagnosis and greater success in treating pathological conditions.

The presence of occult blood in fecal material may indicate gastrointestinal pathology such as hemorrhoids, diverticulitis, fissures, colitis or colorectal cancer. It is essential that patients consult a physician as soon as possible if a positive result is obtained with the test.

ColoCARE is designed to be used as a preliminary screen. Results obtained with ColoCARE cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. It is not intended to replace a regular physician's examination or other diagnostic procedures such as proctosigmoidoscopy, barium enema or X-ray studies.

The American Cancer Society recommends annual fecal occult blood tests 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

The Helena procedure eliminates problems associated with other test such as (1) insolubility of guaiac in water and (2) handling caustic alcoholic peroxide.² The reagents used in this procedure have proven to be comparable to the guaiac methodology, with increased specificity and sensitivity to hemoglobin.^{3,4} Varying levels of water in the toilet bowl do not affect the test since it does not interfere with the surface hemoglobin.

ColoCARE allows an individual to perform the test in the privacy of his home without the inconvenience of handling the specimen or utilizing other items associated with guaiac paper test.

PRINCIPLE

The ColoCARE method is based on the observation that clinically significant amounts of occult blood on a stool sample disperse into the water in the toilet bowl and float to the water surface.² This test was not designed to measure blood in the matrix of the stool, but rather it measures

blood on the surface of the stool sample that disperses into the toilet water.

The test pad consist of a piece of biodegradable paper which has been chemically preprinted with a chromogen. The heme portion of hemoglobin has peroxidase activity which oxidizes the chromogen to form a highly visible blue quinone dye.

The test pad is floated on the surface of the water in the toilet bowl. If detectable blood is present, the hemoglobin will react with chromogen and a blue and/or green color reaction will occur.

The test pad has three reaction sites. The large square is the stool testing area, and the two smaller squares verify that the system is functioning properly. A positive reaction is indicated by the appearance of any blue and/or green color in the large square test area. This same color change will occur in one of the small squares while the other square should remain white.

REAGENT

ColoCARE Pad

Ingredients: Tetramethylbenzidine and cumene hydroperoxide with buffers and stabilizers.

WARNING: FOR IN-VITRO DIAGNOSTIC USE. Do not ingest. Keep out of children's reach.

Storage and Stability: The test pad should be stored at 15 to 30°C and is stable until the expiration date indicated on the package. Protect from moisture, heat, sunlight, and fluorescent light. Do not store the pads in the bathroom or in an area where there is a high humidity or moisture level. Do not refrigerate. If the pad has been damaged or torn, discard the pad. After opening, fold the top of the foil pouch to protect the remaining pads from moisture.

Signs of Deterioration: Discard the pad if the test sites are blue and/or green in color before use.

SPECIMEN COLLECTION AND HANDLING

Specimen: Freshly voided stool. Test three consecutive bowel movements, if possible. If not possible, test 3 bowel movements as close together as possible.

Specimen Collection: Adhere to all precautions given in the "STEP BY STEP METHOD" and "Interfering Substances" Section before performing the test.

Interfering Factors:

1. Red meat or rare-cooked meat: Do not eat red meat or rare-cooked meat for two days prior to testing and during testing.
2. Bleeding due to constipation, hemorrhoids or menstruation: Do not perform the test in the presence of these conditions.

3. Rectal ointments or medications: Avoid using such medications prior to and during testing.
4. Toilet bowl cleaners or deodorizers: Remove cleaners and deodorizers from the toilet bowl prior to testing. Products containing hypochlorite (bleach) or ammonia may cause false positive test results.
5. Vitamin C: Vitamin C levels greater than 250 mg/day may inhibit the color reaction even though blood is present, resulting in a false negative test.
6. Mineral oil laxatives: Mineral oil in laxatives inhibits the color reaction.
7. Medications: Any medication which causes gastrointestinal irritation may give false positive results.

PROCEDURE

Materials Provided:

The following items are provided in the kit.

ColoCARE Office Pack Cat. No. 5651
 50 Patient Envelopes each containing
 3 ColoCARE Test Pads
 1 Instruction Sheet with Reply Card

ColoCARE Hospital Pack Cat. No. 5656
 100 ColoCARE Tests
 1 Instruction Sheet

Preparation for Test

1. For two days prior to testing and throughout the testing period, a normal, well-balanced, unaltered diet which can include well cooked (not rare or raw) chicken, turkey or tuna. Do not eat large amounts of rare-cooked red meat. This can give a false positive test.
2. Discontinue taking Vitamin C.
3. Consult a physician about discontinuing medication. Never discontinue prescribed medication without consulting a physician.

The following medications may cause false positive results:

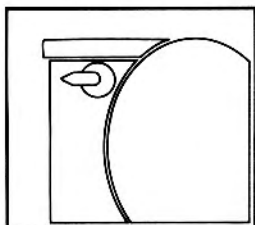
- Aspirin
- Indomethacin
- Corticosteroids
- Phenylbutazone
- Reserpine
- Other gastrointestinal irritants
- Dietary iron supplements
- Antiseptic preparations containing iodine
- Anticoagulants
- Antimetabolites
- Cancer chemotherapeutic drugs

STEP BY STEP METHOD

Patient Instructions

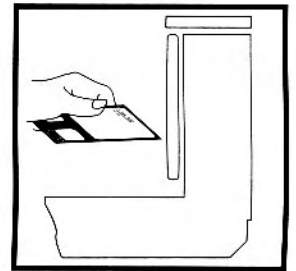
NOTE: Color-blind or visually impaired patients should obtain assistance in reading test results.

1. Remove all cleaners or deodorizers from the toilet bowl and tank. Flush the toilet twice to remove chemicals that may be present. If noticeable color exists, flush until it disappears. Discontinue

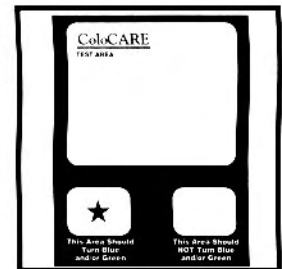
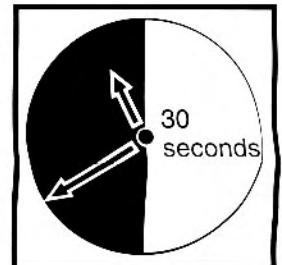


the use of toilet tank/bowl cleaners or deodorizers throughout the test period to avoid interference.

2. Following the bowel movement, do not throw toilet paper into the toilet
3. Perform the test within 5 minutes after the bowel movement.
4. Remove one ColoCARE Test Pad from the protective foil pouch. Fold the open end of the pouch and tape closed to protect the remaining pads from light and moisture. Handle the pad by the edges. With the printed side up, float the pad on the water in the center of the toilet. Refer to note 1 in the "Limitations" Section. If any of the square areas are blue and/or green before being placed in the toilet, discard the test pad.



5. Observe the pad for 30 seconds. Any trace of a blue and/or green color appearing in the large Test Area, is a positive result.
6. The two smaller squares at the bottom of the pad may be used as a guide for color comparison, but the shade or intensity of color may vary from the stool Test Area. One of the two smaller areas will turn blue and/or green (★) and the other one will not. If either of these areas do not perform as described, disregard the results on that pad and place another one in the toilet.



7. Record the test results on the Reply Card as instructed. (The Hospital Pack, Cat. No. 5656, does not include a Reply Card.)
8. After reading and recording the results, flush the pad with bowel movements.
9. Repeat this procedure for the next two bowel movements.
10. Mail the completed Reply Card to your physician.
11. Consult a physician as soon as possible if positive results were obtained.

Recommended Precaution:

If the first ColoCARE test results in a blue and/or green color in the stool test area, immediately perform the following check to assure there were no trace chemicals in the water causing the color change.

1. Flush the toilet twice.

2. Carefully float another ColoCARE pad in the toilet, printed side up.
3. Observe the pad for 30 seconds.
4. A blue and/or green color appearing in the Test Area is indicative of a chemical interference in the water. If the stool test area does not turn blue and/or green, there was no interference from the chemicals in the water.
5. This check is needed only if the first ColoCARE testing shows a blue and/or green color in the stool test area.

RESULTS

A positive test for occult blood is indicated by the appearance of a blue and/or green color in the stool test area. Consult a physician as soon as possible if a positive result is obtained. Be aware that factors other than blood may cause the blue and/or green color change. Some medications and food ingested before and during the test period may cause false positive results. Refer to the "Interfering Factors" section. Final determination of the presence of blood and associated pathology is made by a physician through the use of a physical examination and other diagnostic test.

A negative test for blood is indicated by no color change in the stool test area. This means that the concentration of blood in the stool, at the time of the test, is below the accepted threshold significance of the test. If a patient has a negative test result but has any of the following symptoms, a physician should be contacted promptly for additional testing:

- Any change in bowel habits such as diarrhea or constipation lasting longer than 2 weeks
- Unexplained weight loss lasting 2 or more weeks
- Any sign of blood in the stool (either bright red or black in color)
- Any chronic stomach or bowel pain

EXPECTED VALUES

Individuals free of pathology should have no detectable level of blood in the stool specimen when testing with ColoCARE.

A study was conducted by Helena Laboratories with asymptomatic patients, to determine a rate of expected positive and false positive results. 329 patients were each tested three times with ColoCARE and a standard guaiac paper method. The patient was determined to have a positive test result if any of the tests was positive. ColoCARE and the guaiac method each detected five (5) true positives. The potential for false positive results was 0.9% for ColoCARE and 1.2% for the guaiac method.

LIMITATIONS

1. This test is not designed to measure blood in the matrix of the stool or blood that remains on the surface of the stool in the toilet bowl.
2. Blood in the urine may cause a positive ColoCARE result.
3. A negative result does not necessarily mean the individual is free of colorectal disease since some disorders do not always bleed.

PERFORMANCE CHARACTERISTICS

Sensitivity: Studies were performed on solutions with different concentrations of hemoglobin and iron derivatives. The results indicated that ColoCARE is sensitive to 0.2 mg% hemoglobin and it is not adversely affected by iron compounds in the solution.

Specificity: Refer to the SPECIMEN COLLECTION AND HANDLING and LIMITATIONS sections of the insert.

Comparison: Studies conducted on random specimens collected from a diverse cross section of the population showed excellent comparison between ColoCARE and guaiac slide tests such as ColoScreen and Hemocult®.

ADDITIONAL INFORMATION

Colorectal cancer is usually asymptomatic in the the early stages causing no pain and giving no warning signals other than occult bleeding. However, there are many other causes of rectal bleeding and this symptom is often ignored by both the patient and physician.

The detection of occult blood is critical to many gastrointestinal diseases. Fortunately, it can be detected with the 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 bleeding. Unfortunately, only a small percentage of gastrointestinal diseases 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.

BIBLIOGRAPHY

1. American Cancer Society, Colon and Rectum Cancer, August 1, 2001.
2. Friend, W.G., United States Patent No.4,175,923; Nov. 27, 1979.
3. Guadagno, P.A., Abstract, Amer Assoc for Clin Chem, 1984.
4. Guadagno, P.A., United States Patent 1983.

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Cat. No. 5651

- 50 patient envelopes each containing
- 3 ColoCARE Pads
- 1 Instruction Sheet
- 1 Reply Card

ColoCARE Hospital Pack

Cat. No. 5656

- 100 ColoCARE Pads
- 1 Instruction Sheet

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