

ColoCARE® – Instruction Sheet

Q. What is ColoCARE and how does it work?

A. ColoCARE is a specially prepared pad that has chemicals printed on biodegradable (flushable) paper. These chemicals are sensitive to blood on the surface of the stool. If hidden blood is present in detectable amounts, the stool Test Area will turn blue and/or green. It is recommended that three consecutive stool specimens be tested. If **any one** of the three tests turns blue and/or green, contact your doctor as soon as possible. The Test Area should not change color if blood is not detected.

Q. Why should I use ColoCARE?

A. One of the primary warning signals of many colorectal diseases such as bleeding ulcers, colitis, fissures, diverticulitis, bleeding hemorrhoids, colorectal cancer, and others is hidden blood in the stool. Persons 40 years of age and over and those who have a personal or family history of lower intestinal disorders, colorectal cancers, or other cancers, should have this test yearly or as often as the doctor recommends. This test is not a substitute for a regular physical and rectal examination by your physician, but it may indicate the need for one.

Q. What precautions do I need to take before using the test?

A. Follow all “Pre-test” and “Test” directions on the reverse side of this sheet, in addition to instructions given on this page.

CAUTION: FOR IN-VITRO DIAGNOSTIC USE – Protect the ColoCARE pad from heat, humidity, sunlight, or fluorescent light. Store at room temperature (59° to 86°F). Do not store the pads in the bathroom or in an area where there is a high humidity or moisture level. Do not store the pads in the refrigerator, or in an area where the temperature will exceed 86°F. Keep out of children’s reach. Do not use after expiration date on pouch.

If your first ColoCARE test shows a blue and/or green color in the Test Area, immediately perform this simple check to assure there were no trace chemicals in the water causing the color change.

1. Flush the toilet bowl twice.
2. Carefully float another ColoCARE pad in the toilet, printed side up.
3. Watch the pad for 30 seconds.

If the Test Area turns blue and/or green, this could indicate a chemical interference in the water. If the Test Area does not turn blue and/or green, this is an assurance that your first ColoCARE test did not have any interference from the chemicals in the water. Therefore, you should consult your physician promptly.

REMEMBER: This check is needed only if your first ColoCARE test shows a blue and/or green color in the Test Area.

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. Diarrhea does not affect the test because diarrhea does not interfere with the surface hemoglobin.
3. Varying levels of water in the toilet bowl will not affect the test.

Q. Why should I return the Reply Card if my test is negative?

A. The test is not complete until the Reply Card is returned to the dispensing agent or to your health care professional.

This allows them to:

- verify that the pads performed correctly.
- establish your own personal baseline results at a given time.
- determine the overall screening effectiveness.

ColoCARE[®]

PRE-TEST DIRECTIONS

IMPORTANT NOTE: It is recommended that three consecutive stool specimens be tested. It is important to understand that a positive test result may occur in only one or two of the three tests. All three tests do not have to turn blue and/or green to indicate a positive test for blood in the stool. Any blue and/or green (even the size of a dot) may indicate blood in the stool. **CONTACT YOUR PHYSICIAN** if any of the three pads turn a blue and/or green color in the large square.

Be sure there is ample lighting in the toilet area. If you are color blind or visually impaired, have someone help you read the test. Remove all toilet cleaners, disinfectants, or deodorizers from the toilet bowl and tank. Flush the toilet bowl twice before bowel movement to remove any chemicals. If a noticeable color remains, flush until it disappears.

For two days before and throughout the testing period, you should eat a normal well balanced diet. You can eat well-cooked chicken, tuna, or fish (not rare or raw). Do not eat red meat. Vitamin C (in excess of 250 mg/day) and laxatives (containing mineral oil) may prevent a color change in the test when blood is present, therefore giving a false negative result. Eating red meat and taking the following medications may cause the test pad to turn blue and/or green:

- Aspirin
- Corticosteroids
- Reserpine
- Indomethacin
- Phenylbutozone
- Other gastrointestinal irritants

NOTE: Consult your physician before discontinuing a special diet or prescribed medication.

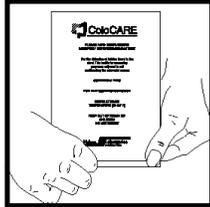
Do not use ColoCARE while you have menstrual bleeding or bleeding hemorrhoids. It is also recommended that you do not use any rectal ointments or medications for 2 days prior to or during the test period.

TEST DIRECTIONS

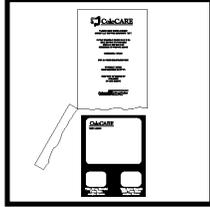
1. Following a bowel movement, do not flush or put toilet paper in the toilet.

PERFORM THE FOLLOWING STEPS WITHIN 5 MINUTES AFTER BOWEL MOVEMENT.

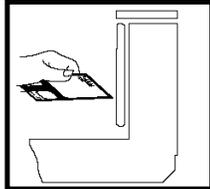
2. Open foil pouch by tearing along the dotted line at the bottom of the pouch, being careful not to tear the pad.



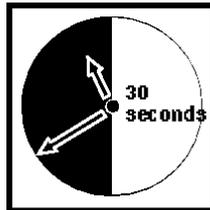
3. Remove one ColoCARE pad from the pouch. Hold the pad along the outer edges. Carefully fold the opened end of the pouch and tape closed to protect the remaining pads from light and moisture.



4. Hold ColoCARE pad with the printed side up. Carefully release the pad, allowing it to float on the water in the center of the toilet bowl.



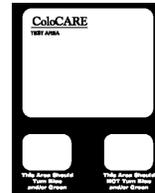
5. Observe the ColoCARE pad for 30 seconds and note any blue and/or green appearance on the pad.



6. The two smaller boxes on the bottom of the ColoCARE pad are there to determine if the ColoCARE pad is working correctly. In 30 seconds, the small box on the left, as shown below, should turn blue and/or green, but the small box on the right should not turn blue and/or green. If these boxes do not work as described above, the pad should be discarded. You will need to repeat the test after the next bowel movement.



Correct



Incorrect - discard pad



7. The test results are determined by the presence of a blue and/or green color in the ColoCARE Test Area (large square at the top of the pad). If color develops in this square, it may not be the same shade or intensity as the smaller square. **Any blue and/or green color in the large square of one or more of the pads may mean blood is present. CONTACT YOUR DOCTOR as soon as possible.**



8. Using the first diagram on the Reply Card provided, mark an "X" in all areas (large and small square areas) that turned a blue and/or green color. Flush the pad and the stool specimen. Repeat this procedure with the next two bowel movements, and mark the appropriate diagram. Return the properly completed card to your dispensing agent or healthcare professional.