

COLORECTAL SCREENING TEST

Instructions

KIT CONTENTS

This **EarlyDETECT™** Colorectal Screening Test Kit contains:

- Sealed pouch containing 5 test tissues and a positive control packet
- Set of instructions

Materials required but not provided:

- Clock or timer

STORAGE & STABILITY

- Store this test kit in its sealed pouch at room temperature (15°–30°C, 59°–86°F).
- Store unused test tissues in the original pouch to protect them from light and moisture before and during testing.
- Do not use this kit after the expiration date printed on the package.

BEFORE YOU BEGIN

- Read these instructions carefully and make sure you understand everything you have to do before you begin the test. In order to get accurate results, you must follow the instructions exactly.
- Do not open the pouch containing the test kit until you are ready to begin the test.
- Verify that the expiration date printed on the package has not passed.
- No dietary restrictions are necessary, but some medications may affect the results of this test. Check first with your doctor to make sure it is all right for you to make any necessary changes in your medication schedule. If your doctor approves, avoid medicines that contain ASA, anti-inflammatory drugs, and rectal ointments for the two days before beginning the test and for the whole time it takes you to complete the three-sample test program.
- Do not perform this test during menstrual bleeding, if you have hemorrhoids that are bleeding, or if you are constipated.

INTENDED USE

The **EarlyDETECT™** Colorectal Screening Test is intended to detect hidden blood in bowel movements, which may indicate a health problem such as bleeding ulcers, hemorrhoids, polyps, colitis, diverticulitis, fissures, or even colon cancer.

In scientific terms, this test uses a pseudo-peroxidase reaction utilizing a chromogen which, when oxidized, produces a distinct blue-green color on a biodegradable paper upon which special reagents have been printed.

INSTRUCTIONS FOR USE

Water Quality Check:

1. Remove all toilet cleaners, disinfectants, and deodorizers from the toilet bowl and tank. Flush the toilet 3–10 times to make sure the water is free of these substances.
2. Cut open the large pouch at the notch. Take one test tissue out of the pouch. Float the test tissue on top of the water. Wait 2 minutes. You should see no blue-green color on the test tissue. If a blue-green color appears on the test tissue, stop. Do not use this toilet for the test; it will not provide accurate results.

Stool Test:

1. If necessary, urinate first then flush the toilet once.
2. Have a bowel movement. Do not flush the toilet.
3. Remove one tissue from the pouch and float it on top of the water. The tissue does not need to touch the stool. Fold and close the opened end of the pouch to protect the remaining tissues from light and moisture.
4. Watch the test tissue for the appearance of a blue-green color in the test area. If it is going to happen, it will appear within 2 minutes. If you are color blind or visually impaired, have someone else read the results.
5. Record the result on the Test Result Card by marking an "X" under the appropriate column for positive with color or for negative with no color.
6. Flush the toilet once. Repeat steps 1 through 5 on your next two bowel movements.

Test Performance Check: (This step must be completed in order for your test results to be valid)

1. Flush the toilet once. Carefully tear open the small foil positive control packet and sprinkle the contents into the toilet while the water is filling up in the bowl.
2. Wait 1 minute, then drop the last test tissue into the toilet. Within 2 minutes, a blue-green colored cross should appear on the tissue. This means that your test tissues have worked properly.
3. Wash your hands.
4. Record the result in the table below. The next time you see your doctor, bring this sheet with you so your doctor can update your health records.

INTERPRETING THE RESULTS

Positive: Any trace of blue-green color visible on the test area (the cross at the centre of the tissue) indicates that blood may be present in your stool. You should discuss this with your doctor, because it may mean that you have a health condition that requires treatment. Sometimes positive results are caused by certain medicines or by other conditions such as menstrual bleeding or bleeding from a hemorrhoid (see "Before You Begin" above), but only a doctor can determine if treatment is necessary.

Negative: No trace of a blue-green color in the test area indicates that at the time of your test there was no detectable blood in your stool. However, some conditions may not cause bleeding all of the time. You should consult your doctor if you have any of the following symptoms: diarrhea or constipation that lasts longer than two weeks, unexplained weight loss, visible blood in your stools at any time, dark black stools, or any other symptom that concerns you.

Record of Test Results			
Test	Date	Result	
		Positive (blue-green color)	Negative (no blue-green color)
Water Quality Check			
1st Stool Test			
2nd Stool Test			
3rd Stool Test			
Test Performance Check (This test should be positive)			

LIMITATIONS OF THIS TEST

- The **EarlyDETECT™** Colorectal Screening Test is limited to the detection of blood in the stool.
- This test is intended for *in vitro* (external) use only.
- Although the test is very accurate in detecting blood in the stool, a small number of false results may occur.
- As with all self-testing devices, a definitive diagnosis should not be made on the basis of a single test. The diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated.
NOTE: If the test result is positive, see your physician to confirm the results and to possibly obtain treatment. If the test results are negative but you are not feeling well or if you are concerned about your colon health, see your physician for possible further testing and diagnosis.
- Each test device can only be used once. Discard it after use.
- This is a screening test and does not replace a regular examination by your physician.
- Do not swallow or inhale the test materials.
- Keep this test kit out of the reach of children.

QUESTIONS & ANSWERS

Q: Why test for water quality?

A: In some regions or on certain days, the water may contain substances that interfere with this test and will give false results.

Q: What does it mean when the result of the Test Performance is orange instead of blue-green?

A: If the positive control powder on the surface of the water does not completely dissolve, it can cause an overreaction with the test tissue and turn orange or rust instead of blue-green. In this case, the test result is considered positive.

Q: What do I do if the Water Quality Check is positive (blue-green)?

A: Wait two or three days, then prepare the toilet as described in step one of the Water Quality Check. Perform the Stool Test again, following from steps 1 through step 6. Skip the Test Performance because you will have one tissue less. If the water check is again positive, the water in your toilet is unsuitable and cannot be used for this test.

Q: If there is only a small speck of blue-green in the test area, is the stool test still positive?

A: Yes. Any visible blue-green color in the test area is considered a positive result.