

Test on blood latent in feaces, FOB Test

Rapid test for the detection of occult blood in feces, does not require the special diet.
Medical device for self-testing.

INTRODUCTION

Fecal occult blood test is a very important and valuable screening test for colorectal cancer. Testing for occult blood in the stool can be done in the lab, but you can do it yourself at home, just using our FOB Test. Currently, it is believed that each person after the age of 35 should perform preventive colorectal cancer tests. The principle of FOB Test is based on antigen-antibody reaction. Applied to the test membrane, in the production process, antibodies react with hemoglobin derived from blood present in the tested stool sample. The test result is read in the form of colored lines on a cassette after 5 minutes

CONTENTS

The package includes equipment necessary to perform one test for the presence of occult blood in the stool:

- » 1 sealed aluminum bag, containing: 1 cassette test and 1 desiccant
- » 1 container with a diluent and applicator to collect stool samples
- » 1 instruction for use

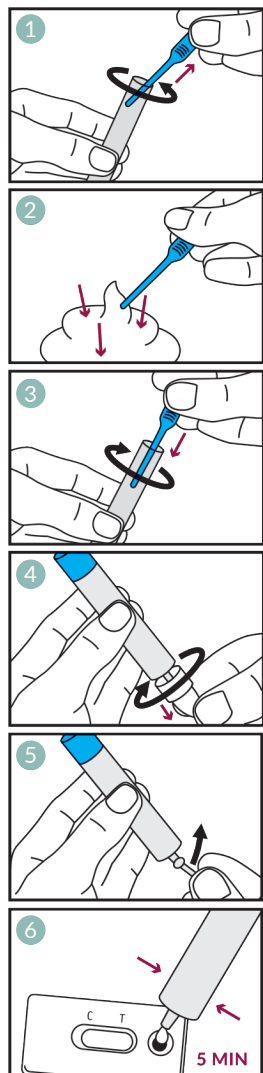
Prepare a watch that will be needed to measure the time of reading the test result, and hygienic tissue helpful in breaking off the tip of the container to collect stool samples.

IMPORTANT NOTES CONCERNING COLLECTION OF STOOL SAMPLE FOR TESTING

- » The stool samples should not be taken during menstruation and up to 3 days after its occurrence.
- » Do not collect the stool samples at the time of bleeding hemorrhoids, the appearance of blood in the urine or in the case of damage of the blood vessel walls when passing stool.
- » In the performance of the FOB Test is not required to use special diet.
- » Alcohol, aspirin and other medicines, especially taken in large amounts, can cause irritation and increased bleeding. For this reason, you should discontinue use of these preparations at least 48 hours before the test (see the answer to the question "What is the specificity of the FOB Test?" later in this leaflet).
- » Performed the test immediately after collection of feces. Do not leave the stool samples at room temperature for a long time.
- » Stool sample can be collected at any time of a day into any utensil, thoroughly washed and dried.

Test must be performed in strict compliance with the instructions below:

If the test was stored at 2 - 8°C, for half an hour before the test you should remove it from the refrigerator and bring its temperature to room temperature.



COLLECTION OF STOOL SAMPLE FOR TESTING

» Pick up the stool sampling container so that the blue cap is on top and the white one at the bottom. Remove the blue cap and using the applicator placed in the cap collect stool sample.❶

» To collect stool sample for testing "screw" the tip of the applicator at three different places of the tested stool, to a depth of approximately 1 cm.❷ It should be noted that the feces must cover the surface of the applicator only a thin layer.

Note: Too much stool on the applicator which is later introduced into the container with a diluent may give invalid test result

» Place the applicator with collected stool sample back into the container with a diluent, tightly screw the cap and shake vigorously to mix thoroughly.❸

TEST PERFORMANCE

» Remove the cassette test from aluminum bag and place it on a level surface. In the bag there is also a desiccant, which must be thrown into household garbage. The test should be completed within an hour.

» While holding the sampling container as before (blue cap at the top, white cap at the bottom) unscrew this time the white cap that secures the tip of the container against accidental breakage.❹

» Shake the container vigorously to thoroughly mix the stool sample with diluent. Then, grab the tip of the container through the hygienic tissue and break it.❺

» Squeezing the container wall place **3 full drops** of the solution on the round window of the test plate. During the dripping, do not touch the tip to the test plate.❻ **Start time measurement.**

» Read the test result after **5 minutes**. Do not take into account the result obtained after a period longer than 10 minutes.

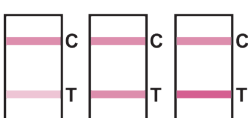
Pour the rest of the sample liquid from the container into the toilet and rinse it with water. After the reading of the test result, throw the test and empty container into the household garbage.

INTERPRETATION OF TEST RESULTS



NEGATIVE RESULT

In the result window there appears only one line: control line C. The test line T does not appear. Occult blood was not detected in the test sample.



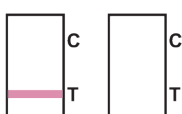
POSITIVE RESULT

In the resulting window, there are two stained pink lines: control C and test T.

The color intensity of the test line T does not matter.

The test T line may be weaker, the same or stronger than the control line C. Even a very weak T line should be interpreted as a positive test.

In the tested sample occult blood was found.



INVALID RESULT

In the resulting window no line appears or only test line T. In this case, the interpretation of the test result is not possible and the test should be repeated with a new sample of feces and using a new test.

PRECAUTIONS

- » Test is for external use only.
- » FOB Test package should be stored at 2-30 °C. Do not freeze.
- » Do not use the test kit after the expiry date shown on the packaging.
- » Do not use the test if the bag is damaged, because the moisture from the air can damage the test.
- » The test is intended for single use only.
- » Dispose of the used test like any other household waste.
- » Keep the test out of the reach of children.

FREQUENTLY ASKED QUESTIONS

Who should make tests for occult blood in the stool?

Testing for fecal occult blood should be performed in patients who observe symptoms associated with colon diseases.

People over 35 years of age, even if they do not have this type of symptoms, should perform testing for occult blood in the stool once a year, while in the case of persons aged 50 such studies are a must.

Indication for testing for occult blood in the stool are also family predispositions, since approximately 10% of cases of colorectal cancer have a family nature. When there is a family history of colon cancer, test for occult blood in the stool should be performed in patients after 25 years of age

What are the symptoms associated with diseases of the colon?

The symptoms associated with diseases of the colon are: a sense of incomplete defecation, incontinence and gases, pain during bowel movement, mucoid stools, pain in the lower abdomen, unintended loss of weight, stomach flatulence, loss of appetite, change in bowel habits, alternating diarrhea and constipation or enlargement of the liver.

What does a negative FOB Test result mean?

A negative test result means that the fecal occult blood was not detected in the sample.

Receiving a negative test result does not exclude the presence of polyps, because the bleeding of them may be at an instantaneous stop. To increase the chance of detecting bleeding polyps, it is recommended to repeat the test a second time and even third time after a few days, using the new tests.

However, if symptoms consistent with diseases of the colon persist, despite receiving negative test results, you should go to your family doctor.

What does a positive FOB Test result mean?

FOB Test positive result means that occult blood was detected in a test sample of feces.

The detection of occult blood in the stool may indicate bleeding from polyps, which most often presence leads to colorectal cancer.

The presence of blood in stool may also accompany other illnesses, such as hemorrhoids, blood in the urine, gastric diseases. Always, however, in the case of a positive result the person concerned should consult his/her family doctor, surgeon-oncologist, oncologist, gastroenterologist or a proctologist.

How sensitive of FOB TEST?

Small amounts of blood in the stool may also be present in healthy people, who do not have the problems associated with the colon. Sensitivity of FOB Test is set to detect only the amount of blood that indicate disease processes and is 40 ng hemoglobin in 1 mL of extraction solution.

What is the specificity of the FOB TEST?

FOB Test for the detection of fecal occult blood is specific for human hemoglobin.

The study shows that it does not detect blood hemoglobin of ox, pig, chicken, turkey, goat, horse and rabbit (at a concentration of 1 mg/mL). For this reason, the performance test of the FOB Test does not require the special diet. However, taking, for example, iron-containing dietary supplements or drugs containing substances "diluting" the blood, such as acetylsalicylic acid (such as Bayer Aspirin®) and coumarins (e.g. Macumar®), may cause increased blood secretion. Therefore, persons using similar preparations should not during the treatment perform tests for fecal occult blood.

What does the line that appears at the letter C on a cassette test mean?

It is the control line. The appearance of a colored stripe at letter C indicates that the test is working properly, as well as the test is done properly.

Should the line that appears at the letter T be as strong as the control line C?

The line that appears at the letter T does not have to be as strong as the control line C. Test line T can be stronger or weaker than the control line C. Even if the test line T is very weak, the test result should be interpreted as positive.

To summarize: if the result window shows two lines (control and test), regardless of their intensity, the test result should be interpreted as positive.

Are the results of FOB Test reliable?







The result obtained using the FOB Test is reliable if the instruction for use and the time of reading the test result are carefully observed.

Date of the last revision of the instruction: 20.07.2022

Version 7 BS_AT/EN

SYMBOLS

CE 1434

	Prior to test performance carefully read the instruction		For in vitro diagnostics
	For single use only		Store at temperature 2-30°C
	Serial number		Expiry date



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