

FOBCHECK®

Rapid diagnostic test for the detection of fecal occult blood

Rapid diagnostic test for the detection of fecal occult blood. For in vitro diagnostic use – for self-testing.

Please read the instruction sheet carefully before performing the test.

INTENDED USE

The device is useful to detect blood found in a number of gastrointestinal disorders, e. g. diverticulitis, colitis, polyps, and colorectal cancer. It is intended for self-testing by laypersons as an aid in the diagnosis of lower gastrointestinal disorders. The FOBCHECK® One-step Fecal Occult Blood Test detects 40 µg/L human Hb as the threshold level.

PRECAUTIONS

- Test instructions must be followed precisely to insure accurate results.
- For in vitro diagnostic use. Not to be taken internally.
- Do not use after the expiration date.
- Do not open the test kit foil pouch until you are ready to perform the assay. The test kit should remain in the sealed pouch until use.
- Keep out of the reach of children.
- Store in a dry place at 4–30°C. Foil pouch should be at room temperature before opening.
- Do not freeze.
- Please wash hand before and after performing the assay.
- Discard the used kit into the wastepaper basket or trashcan.
- The following facts may affect the result: bleeding hemorrhoids, blood in urine, stomach irritation. So do not test during your menstrual period or take the drugs in 7 days before the test which may cause the colon bleeding, such as Aspirin, some anti-inflammatory drugs or Ibuprofen.

HOW TO USE

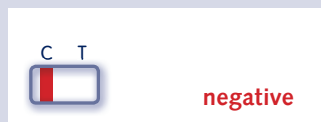
1. Collect your stool specimen in a clean, dry container free from detergents and the assay should be performed immediately. It is best to catch your feces before it enters the toilet. You can do this by holding a piece of toilet paper in your hand. After you catch it, transfer it to the container.
2. Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter suspension from container.
3. Take sample from various surfaces of the stool specimen by the applicator stick. It is necessary to filling the sample up the ditch, but not too much.

4. Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the Sample Collection Tube.
5. Remove the test device from the foil pouch and use it as soon as possible.
6. Shake the collection tube thoroughly (5–10 times) to ensure proper mixing of the fecal sample with the extraction solution (no big grain).
7. Take down the cap of the collection tube. Using a piece of tissue paper, break the tip of the collection tube using a twisting motion. Be careful not to spill or spatter suspension.
8. Hold the collection tube vertically and dispense 3 drops (approximately 150 µl) of suspension into the sample well of the test device.
9. As the test begins to work, you may notice a light red flow moving across the Test and Control windows. The test result should be read within 5 minutes. Do not read the result after 5 minutes.

HOW TO READ THE RESULT



Two red lines are visible in the control („C“) and test („T“) region of the test window. The intensity of the test line may be less than that of the control line; this still means positive result.



The control line („C“) appears in the test window, but the test line is not visible.



The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing device.

FAQs

What is fecal occult blood?

Fecal occult blood is blood in your feces that you cannot see in your stool or on your toilet paper after you use the toilet. FOBCHECK® is designed to detect it.

Why should you do this test?

You should do this test, because blood in your feces may be an early sign of a digestive tract disorder, for example abnormal growths (polyps) or cancer in your colon.

How often should you test for fecal occult blood?

It is recommended that you test for fecal occult blood every year after you turn 50. Some doctors suggest that you start testing at age 40, if your family is thought to be at increased risk. Follow your doctor's recommendations about how often you test for fecal occult blood.

How accurate is this test?

This test is about as accurate as the test your doctor uses, but you must follow the directions carefully. For accurate results, you must prepare properly for the test and get a good stool sample.

Why does the occult blood level of the test matter?

Basically FOB tests that detect the lowest concentration of human Hb can give you the earliest results of digestive tract disorders. FOBCHECK® could

detect 40 µg/l human blood hemoglobin in sample.

What if the lines in the windows are different shades of pink?

As long as 2 parallel lines appear, the result is positive, even if the two lines are different shades of pink.

Does a positive test mean you have hidden blood in your stool?

No. A positive result means that the test has detected blood. This does not mean you have tested positive for cancer or any other illness. So if the result shows the positive result, further testing and examinations should be performed by the physician to determine the exact cause and source of the occult blood in the stool.

If the test results are negative, can you be sure that you do not have a bowel condition?








No. You could still have bowel condition that you should know about. You should use this test again after a while. This is necessary because if you have polyps, they may not bleed all the time.

Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.

NanoRepro encourages you to take the following steps to increase testing accuracy.

- Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.
- If you get a positive result, it is advisable to visit your doctor **immediately** to determine the exact cause and source of the occult blood in the stool.

www.fobcheck.com

 Follow instructions	 For in vitro diagnostic use	 See overprint on box
 Store at 4–30°C DO NOT FREEZE	 Tests per package	 Do not reuse
		 See overprint on box