

## MiraTes Bowel (FOB) HomeTest – Information

Blood in stool is reason for alertness. Although this may not always be a reason for serious concern, it is important to determine the cause. Causes can be, for instance, small wounds in the digestive system, haemorrhoids, intestinal inflammation, but also Crohn's disease, bowel polyps, and bowel cancer. Often, blood is present in stool well before complaints are experienced. However, in many cases the amount of blood is so small that it cannot be detected with the eye. The Bowel (FOB) HomeTest makes it possible to detect hidden blood in stool (faecal occult blood – FOB). This way, possible bowel disorders may be discovered earlier, which enables treatment at an early stage.

Especially in case of bowel cancer, it is important to start treatment at an early stage. Bowel cancer often shows symptoms or complaints when it is in an advanced stage. Bowel cancer often causes no signs or symptoms until it is fairly advanced. However, early small cancers often bleed slightly into the intestines without causing noticeable discomfort. In several European countries, preventive screening are held to increase the number of early discoveries and cures of bowel cancer.

The MiraTes Bowel (FOB) HomeTest enables you to detect blood in stool. This way, the cause can be discovered earlier and, if necessary, treated.

### What is cancer?

Cancer is a collection of more than 100 different diseases. All these different types of cancer have one characteristic in common: uncontrolled cell division.

The human body continuously produces new cells for growth and replacement of damaged and old cells. New cells are made by cell division over a million times a day. This process is strictly regulated by the human body.

Uncontrolled cell division is caused by damage (or mutations) to the cell's DNA. Because DNA contains all genetic information for cell development, such a mutation may cause a normal cell to abnormally grow in a tissue or organ.

A transformation from a normal cell into an uncontrolled growing (cancer) cell can be either benign or malignant. In general, benign cancers do not invade or spread and are not life threatening. Examples are warts, moles and polyps in the colon or rectum. However, the life threatening malignant forms of cancer are able to spread to and invade other parts of the human body.

Certain chemicals or physical agents (carcinogens) may cause damage to the cell's DNA, and are therefore risk factors for developing cancer. Tobacco smoke and alcohol are examples of carcinogens. Radio active material and certain viruses may also trigger uncontrolled cell division. Sometimes a cancer may develop spontaneously or may be caused by genetic factors.

### What is bowel cancer?

Bowel cancer is the malignant growth that starts on the inside wall of the large intestine (colon) or the rectum (end of the colon). It is also referred to as colon, rectal or colorectal cancer. It can grow for a relative long time before spreading to other parts of the body.

### What are polyps?

Most bowel cancers are thought to arise from polyps. These mushroom-like growths are usually benign, but over a long period of time (several years) some may become malignant. In later stages of the disease, cancerous polyps may penetrate the bowel walls and spread to nearby lymph nodes and other organs.

Because polyps may be small and produce few (if any) symptoms, it's important to regularly perform a screening test to help detect polyps and prevent bowel cancer on the long term.

### Signs and symptoms of bowel cancer

Many people with bowel cancer have no symptoms in the early stages of the disease. When symptoms occur, they are likely to vary, depending on the cancer's size and location in your intestine.

If signs and symptoms of bowel cancer do appear, they may include change of bowel habits, blood in your stool, persistent cramping, gas or abdominal pain. Currently, the most important early indicator of bowel cancer is blood in faeces. These symptoms may also be caused by other diseases than bowel cancer.

### Risk factors

Bowel cancers may occur at any age. No one is too young to develop bowel cancer. However, about 90% of people with the disease are older than 50. Risk factors other than age include:

- *diet*; a fat-rich diet (especially from animal origin), red meats and processed meats increases the risk of bowel cancer; many fruits and vegetables however may lower the risk;
  - *unhealthy lifestyle*, for example smoking, heavy alcohol consumption, not enough physical exercise;
  - *diabetes*; people with diabetes have an increased risk to develop bowel cancer;
  - *inflammatory bowel diseases*, chronic diseases such as ulcerative colitis and Crohn's;
  - *personal history of polyps or bowel cancer*, if you have had polyps or colorectal cancer, even though it has been completely removed, you are at increased risk to develop bowel cancer;
  - *family history*, an increased genetic susceptibility plays an important role in approximately 5% of patients with bowel cancer;
- Performing the MiraTes Bowel (FOB) HomeTest annually, along with a few simple changes in your diet and lifestyle, may dramatically reduce your overall risk of developing bowel cancer.

### Who should use the MiraTes Bowel (FOB) HomeTest?

The MiraTes Bowel (FOB) HomeTest should be used by people aged 50 years and older. You may need to use the test earlier if other risk factors are present. It is recommended to perform the test annually.

### How does the MiraTes Bowel (FOB) HomeTest work?

The MiraTes Bowel (FOB) HomeTest offers a convenient and hygienic way to detect the presence of occult (hidden) blood in faeces. This is one of the earliest signals of polyps, inflammatory bowel diseases and bowel cancer. The MiraTes Bowel (FOB) HomeTest

therefore helps to increase the opportunity of detecting these diseases in their beginning or early stage.

The MiraTes Bowel (FOB) HomeTest uses a combination of antibodies to detect human haemoglobin. The test is very sensitive to detect even a single drop of blood in faeces. Read the instructions for use carefully before performing the test.

The MiraTes Bowel (FOB) HomeTest is performed by collecting a sample of faeces with the included stool collection device. When the stool collection device is put back into the sampling tube, it can be screwed onto the test strip tube. After a few minutes, the results can be read from the coloured lines that appear.

### Reliability

Both consumer and laboratory studies have shown that the MiraTes Bowel (FOB) HomeTest has an overall accuracy of 99% for detecting blood in stool. A positive result with the Bowel (FOB) HomeTest means that blood has been detected. The cause for this cannot be determined from the test result and may vary from small wounds in the digestive system, haemorrhoids, intestinal inflammation, Crohn's disease, bowel polyps, or bowel cancer.

### How should the test result be interpreted?

Under normal circumstances no blood will be present in faeces. Small wounds in the intestinal system and a number of gastro-intestinal disorders, e.g. diverticulitis, colitis, polyps and bowel cancer, may cause blood in faeces.

If blood is detected in your faeces, the MiraTes Bowel (FOB) HomeTest will show two red test lines. This is called a positive result, and should always be a reason to see your doctor for further investigation. Take this test and the instructions for use with you.

If no blood is detected in your faeces, the MiraTes Bowel (FOB) HomeTest will just one red test line. This is called a negative result. Since bowel disorders may not bleed in stool continuously, the presence of bowel disorders cannot be excluded. It is therefore recommended to perform this test annually to increase the chance of early detection.

For more background information about the test result, please read the "Considerations before use"-section.

### Counselling

If you experience physical complaints, regardless of the outcome of this test, we advise you to contact your doctor. As with all diagnostic tests, the definitive clinical diagnosis must not be based on a single test result, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

### Considerations before use

Scientific data do not currently suggest that there is a single "best test" for any person. A test for blood in stool is used in various European public screening programs for bowel cancer. However, this method has both advantages and disadvantages.

The problem is that not all cancers bleed, and those that do often bleed intermittently. Furthermore, most polyps don't bleed. This may result in a negative result, even though you may have polyps. On the other hand, if blood shows up in faeces, it may be the results of small wounds in the intestinal system, haemorrhoids or an intestinal condition other than cancer.

### Usage and storage

The MiraTes Bowel (FOB) HomeTest should not be used during or within 3 days of a menstrual period, or when you are suffering from bleeding haemorrhoids or blood in the urine. Alcohol, aspirin, indomethacin, reserpin, phenylbutazone, corticosteroids and other medications may cause gastro-intestinal irritation resulting in occult bleeding. *Only* with your doctor's approval, such medication should be discontinued for 7 days before and throughout the test period. Rectal medication should also be discontinued (with doctor's approval). Dietary restrictions are not necessary. Raw beef, vitamin C and alcohol do not affect the test result.

The MiraTes Bowel (FOB) HomeTest should be stored in the sealed pouch at room temperature or in the refrigerator (2-30°C). Keep out of the reach of children. Do not freeze the MiraTes Bowel (FOB) HomeTest. Before performing the test, make sure it is at room temperature (15-30°C). Do not use the test after its expiration date (see packaging). The MiraTes Bowel (FOB) HomeTest is designed for preliminary screening and should not replace other diagnostic procedures such as colonoscopy and sigmoidoscopy.

### Product guarantee

MiraTes guarantees the quality of this test, if used according to the enclosed instructions for use. In case the sealed pouch has reached you opened, or when parts described in the instructions for use are missing or damaged, please return the unused components of this test to the address below. MiraTes will replace it free of charge.

### Periodically testing - reminder service

An annual Bowel (FOB) HomeTest is recommended for everyone older than 50 years. You may need to use the test earlier if other risk factors are present. MiraTes offers a free reminder service for your annual Bowel (FOB) HomeTest. To subscribe to this service, simply send an email to [remind\\_me@mirates.com](mailto:remind_me@mirates.com).

Visit our website for more information about our products:  
[www.mirates.com](http://www.mirates.com) / [www.mirates.co.uk](http://www.mirates.co.uk)



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# MiraTes Bowel (FOB) HomeTest – Instructions for Use

## Content



## Materials required but not provided

Clock, watch or timer.

## Step 1: Preparations for use

When stored in the refrigerator, allow the MiraTes Bowel (FOB) HomeTest to adjust to room temperature (15-30°C) prior to testing. Open the sealed pouch when you are at step 3 and use the test as soon as possible. The silica gel should not be used and can be thrown away.

## Step 2: Sample collection

**Attention!** Please avoid urine and excessive dilution of the faecal sample with water from the toilet bowl. This may cause erroneous results.

A



**A:** Take the sampling tube and remove the sampling lid. Keep the sampling tube in a vertical position to prevent the loss of any solution.

**B:** Hold the sampling lid by the Thumb Grip. Use the tip of the sampling lid to collect a moderate amount of faecal sample at two or more sites. Only take the faecal sample that sticks to the sampling lid and never intentionally take any additional piece of faecal sample into the tube.

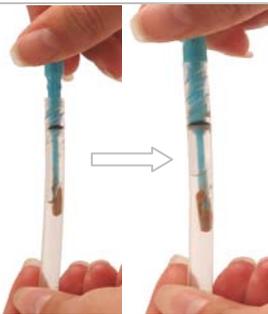
B



Too much

Just right

C



**C:** Insert and screw the sampling lid back into the sampling tube in a vertical position. Do not spill any solution from the tube. Tightly seal the lid with the tube.

## Step 3: Sample preparation



Shake to dissolve the stool into solution. Turn the sampling tube upside down vertically.

Open the foil pouch and use the test strip tube within 30 minutes. You can throw away the silica gel (desiccant).

## Step 4: Test activation



Screw the test strip tube in a vertical position into the sampling tube until both tubes are tightly sealed together.

Allow the solution to flow into the bottom space of test strip, keeping the device in a vertical position.

### Attention!

If the solution does not flow into the bottom space of the test strip, turn the tubes slightly.

You may soon see a red fluid moving across the white area of the test strip.

**Attention!** Read test result 5-10 minutes after test activation.

## Step 5: Reading the result

Because the result may change if left standing for a certain period of time, it is recommended to read the test 5-10 minutes after test activation. A negative result should read directly. A positive result will last for at least 24 hours.

### Negative result (no blood detected in faeces):



If no blood is detected in your faeces, the MiraTes Bowel (FOB) HomeTest will just one red test line. This is called a *negative result*. Since, with bowel disorders, blood may not be in stool at all times, the presence of bowel disorders cannot be excluded. It is therefore recommended to perform this test annually to increase the chance of early detection.

### Positive result (blood detected in faeces):

If blood is detected in your faeces, the MiraTes Bowel (FOB) HomeTest will show two red test lines. This is called a *positive result*, and should always be a reason to see your doctor for further investigation. This does not always have to be reason for concern, whereas blood in stool may have various innocent causes. Take this test and the instructions for use with you.

### Invalid result:

If no test line appears at all, the test result is *invalid*. Insufficient amounts of faeces or incorrect procedural performance are the most likely reasons for an invalid test result. In case this can be excluded, please contact MiraTes directly.

Do not throw away the test and the package.

## Disposal

After successful use place the different components of the MiraTes Bowel (FOB) HomeTest into the original box and secure the lid. Dispose the box in your dustbin.

## Service

MiraTes produces and delivers its products with the utmost care. In order to continue delivering high quality products and service, we are pleased to receive your feedback. You can send us questions and remarks via the service form on our website [www.mirates.com](http://www.mirates.com) / [www.mirates.co.uk](http://www.mirates.co.uk). We will deal with your questions as soon as possible. Should you have any questions about the performance of the test or the meaning of the test result, you can find answers to your questions in our FAQ section on our website.



MiraTes Europe BV  
Caïrostraat 60  
3047 BC Rotterdam  
The Netherlands

T +31 (0) 10-262 13 38  
F +31 (0) 10-262 43 71  
E [service@mirates.com](mailto:service@mirates.com)  
I [www.mirates.com](http://www.mirates.com)



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store between 2-30°C



contains sufficient for 1 test



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this product is in conformity with the provisions of European Directive 98/79/EC