



Introduction

Colon cancer is one of the most commonly occurring cancers in Europe. It develops over years and the early stages often show no symptoms at all. By early detection of occult (invisible) blood in the stool, colon cancer can be detected early and the death rate can be reduced.

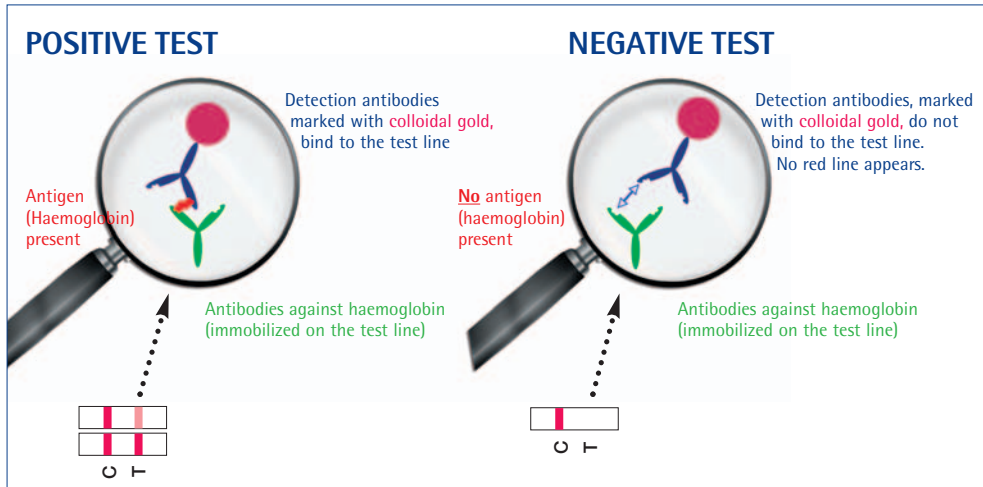
Polyps, large intestine inflammation, diverticulitis, fissures and colon cancer in the large and small intestines have fine and very sensitive blood vessels – so sensitive that they can be damaged by the passing of stools alone, and small amounts of blood invisible to the eye can be passed into the stool. The FOB rapid test detects the smallest amounts of occult blood with specific antibodies and gives more accurate and reliable results than chemical tests. The result of the FOB test cannot be affected by previous consumption of certain foods e.g.

meat or some types of vegetables, so that the no special dietary measures are necessary prior to carrying out the test. The detection limit is 50 ng/ml for haemoglobin or 2µg/g haemoglobin/g stool.

Principle of the test

The new ulti med FOB test detects human haemoglobin (the red colour present in blood) exclusively via a specific antibody reaction. If haemoglobin is present in the stool sample, it reacts with specific antibodies in the test cassette that are bound to gold particles (see illustration right). This complex migrates along the membrane and reaches the test line (T), on which another haemoglobin antibody is bound. With a positive result the gold marked antibody-laden haemoglobin molecules from the stool sample are bound in the test zone (T). A red coloured T-line is observed.

With a negative result there are no haemoglobin molecules that can bind as a complex on the test line (T) and a coloration does not appear. Marked antibodies are however bound to the control line (C), so it always appears and serves as confirmation that the test has been carried out correctly.



Please read carefully before use!

Materials provided

- 1 FOB test cassette
 - 1 stool collection tube
 - 1 stool sample collection unit
 - 1 test instruction
- You will also need a stopwatch

Storage and stability

The test kit and the FOB test can be stored at 2 – 30°C. The test cassette must be used within 10 minutes after removal from the foil pouch.

The test and the buffer may be stored until the expiry date printed on the pack.

- Do not freeze
- Do not use after the expiry date

Notes

- All stool samples should be treated as infectious material.
- For in vitro diagnostics only, do not ingest!
- Do not touch the test membrane in the result window!
- Do not use if the protective foil of the test cassette is damaged.
- Do not use test after the expiry date.
- Keep the test cassette in the sealed protective foil until required.
- The test membrane must not come into contact with liquid. High moisture and temperatures can affect the result.
- Do not eat, drink or smoke whilst preparing and carrying out the test. If possible use disposable gloves and wash and disinfect hands after carrying out the test.
- Keep out of reach of children.

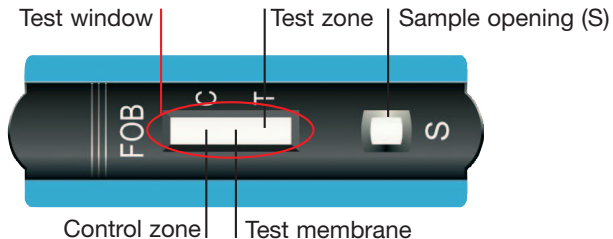
Stool sampling and preparation

- Stool samples should not be taken during menstruation or 3 days before or after your period, or in the case of bleeding caused by constipation, bleeding haemorrhoids or when using rectal medications. This could lead to false positive results.
- Alcohol and certain medicines such as for example aspirin, corticosteroids and anti-inflammatory medicines can lead to bleeding in the gastrointestinal tract and give a false positive result. These substances and medicines should be discontinued 48 hours before carrying out the test.
- The observation of a particular diet before the test is not necessary.

Sample collection

The stool sample is taken with the aid of the stool sample collection unit. Instructions for use are printed on the cassette itself.

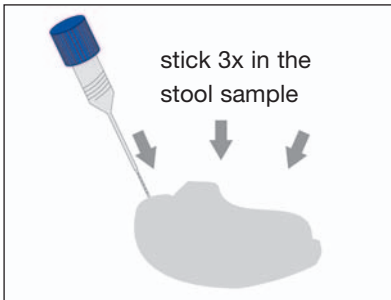
Important: The stool sample should not come into contact with urine or water from the toilet. This can give a false test result.



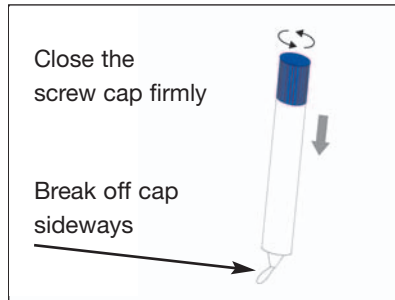
Sample Collection



1. Remove the stool collection tube from the stool sampling set and unscrew the cap. The stool sample is taken using the spiral stick attached to the screw cap.

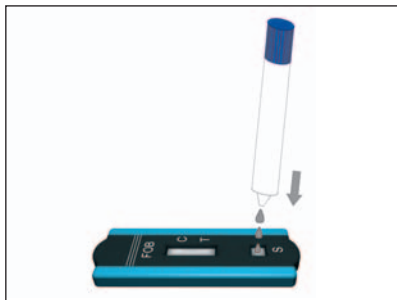


2. Insert the spiral stick in three different places in the stool sample. Sufficient sample for the test is collected in the grooves, the result is not improved by collecting larger amounts of sample.



3. Next place the spiral stick back in the sample tube and close the screw cap firmly. Label the sample tube or the envelope provided in the stool sampling set.

Test procedure



4. After you have broken off the cap sideways, add 3 full drops of solution to the round, smaller sample trough/ opening of the test cassette and read the results after 8 minutes.

Warning: the stool collection tube contains a buffer solution in which the stool sample can be kept for 3 – 4 days at a temperature of +2°C to + 8°C.

Test implementation

The FOB test cassette and the stool collection tube should be allowed to come to room temperature before carrying out the test. Remove the test cassette from the pack shortly before carrying out the test.

Ensure that the test cassette is at room temperature, to prevent accumulation of moisture on the membrane. Place the test cassette on an even surface. Carefully shake the stool collection tube to mix the stool sample on the spiral stick with the buffer. Using a paper towel to avoid droplets break off the tip of the stool collection tube. Keep the stool collection tube upright, to avoid spilling the sample.

Add 3 full drops of the solution to the round smaller sample well of the test cassette and read the results after 8 minutes.

The results cannot be read after more than 10 minutes. The test is valid if the red control line (C) is observed.

Test evaluation and interpretation of the results

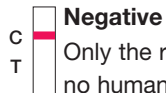
Warning! Do not evaluate the test yourself if you suffer from impaired vision! For correct evaluation of the test, it is important to compare the intensities of the lines carefully.



Positive

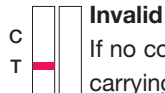
Both the control line (C) and the test line (T) appear.

The **intensity** of the test line is **not** important. **A weak test line is also a positive result!** This means that human blood is present in the sample.



Negative

Only the red control line (C) appears. This means that no human blood above the detection limit is present in the sample.



Invalid

If no control line (C) is visible in the result window after carrying out the test, even if a test line is present, the test is invalid. This may be due to not enough sample or a error when carrying out the test. Repeat the test with a new test cassette.

Limitations

The FOB rapid test is only intended for in vitro diagnostics. It must only be used for the detection of occult blood in stool samples.

The ulti med FOB test provides reliable detection of haemoglobin, but this is only a sign for the presence of colon cancer. A negative test result cannot completely exclude colon cancer. **If you still have cause for concern, consult your doctor.**





Positive test results can also be caused by harmless conditions (for example blood can commonly be found in the stools during menstruation or if haemorrhoids are present). Do not make any medical decisions without consulting your doctor.

Sensitivity and specificity

The ulti med FOB test reacts specifically with human haemoglobin and has a detection limit of 50ng/ml haemoglobin or 2µg/g stool.

It shows no cross-reaction with animal haemoglobin or with bilirubin, vitamin C and other antioxidants or horseradish peroxidase.

Rev. L_EW 05/2007

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|  Manufacturer |  Use only once |  Contents |  Use until |
|  Only for in vitro diagnostic purposes |  Observe instructions |  Batch number |  Storage temperature |



FOB TEST

010H100



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