

FOB TEST CASSETTE 010A200-12



ulti med Faecal Occult Blood (Stool) Test Cassette

SUMMARY

Many times gastro-intestinal diseases are not recognised. In Europe colon cancer is one of the most common cancer types. Colon cancer can be diagnosed by continuous preventive examinations at an early stage and in most cases it can be healed. By an early and reliable detection of occult blood in stool, colon cancer can be recognised early and reduce the mortality rate of patients suffering from colon cancer. Colon cancer develops over years and the early stages usually do not cause any afflictions. Polyps, colitis, diverticulitis, fissures and colon cancer have fine and very sensitive blood vessels – that sensitive that they can be damaged by the passing stool and release small quantities of blood to the stool that cannot be recognised visually. The FOB advanced test detects even smallest amounts of occult blood by specific antibodies and provides for more exact and more reliable results than chemical occult blood tests (guaiac tests). The FOB advanced test cannot lead to false results due to certain nourishment such as meat, vitamins and others. There are no necessary dietary restrictions to be observed prior to taking the test.

PRINCIPLE

The new immunologic FOB advanced test is a rapid chromatographic immunoassay, which detects exclusively human haemoglobin by a specific antibody reaction. The haemoglobin that is contained in the stool sample reacts with specific mono- and polyclonal antibodies, which are attached to colloidal particles. This complex disperses on the membrane and reaches the test line (T) that contains anti-haemoglobin. On a positive result the haemoglobin molecules from the stool sample that are loaded with colloidal antibodies are attached to the test line (T) and become visible by a red colouration. On a negative result there are no haemoglobin molecules that can attach to the test line (T) and therefore there will not be any colouration of the test line (T). The control line (C) ensures by a red colouration that the sample application and membrane wicking has occurred correctly and that the test result is valid.

INTENDED USE

The ulti med faecal occult blood test is an in-vitro immuno-chromatographic assay for qualitative detection of human haemoglobin in faeces. It is intended for professional use only. The test sensitivity for human occult blood in faeces is 50 ng/ml.

MATERIALS PROVIDED

The ulti med FOB (Faecal Occult Blood) test kit contains the following items to perform the test:

- 12 FOB test cassette in foil pouch
- Instructions (1 per kit box)
- Stool collection tube (each tube contains extraction buffer of 2 ml 0,1M TBS with BSA and 0,02% sodium azide, 12 bottles per Kit)
- Stool sample collection unit (12 per Kit)

MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch

WARNINGS

1. For in vitro diagnostic use only.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not re-use the test kit.
4. Do not use it beyond the expiration date.
5. Do not eat or smoke while handling specimens.
6. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
7. Avoid splashing or aerosol formation.
8. Clean up spills thoroughly using an appropriate disinfectant.
9. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

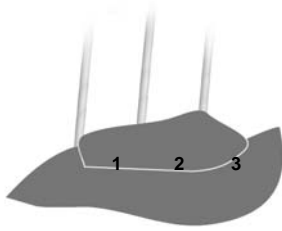
STORAGE AND STABILITY

The (FOB) test kit must be stored at 4-30°C. Do not freeze. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch.

SPECIMEN COLLECTION AND PATIENT PREPARATION

1. Only faecal specimens should be used in this assay. They can be collected from the sample collection unit provided with the test. Specimen should avoid contamination of toilet water.
2. Dietary restrictions are not required, but alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.
3. Specimen collection should not be performed during or three days before or after a menstrual period, or if the patient suffers from bleeding haemorrhoids or blood in the urine, false-positive test results may be obtained.
4. Unscrew the top of the sample collection device and use the sample collection stick to collect stool sample by dipping the stick randomly into 3 different places of the same stool sample (see image next page).
Important: Make sure you collect sufficient stool sample. Too little stool sample may cause false negatives!
5. Put the sample collection stick containing the sample back into the sample collection device and screw it tightly. Shake it very well.
6. Sample collected can be stored at room temperature (below 30°C) for 14 days or refrigerated at 4 to 8°C for one month.

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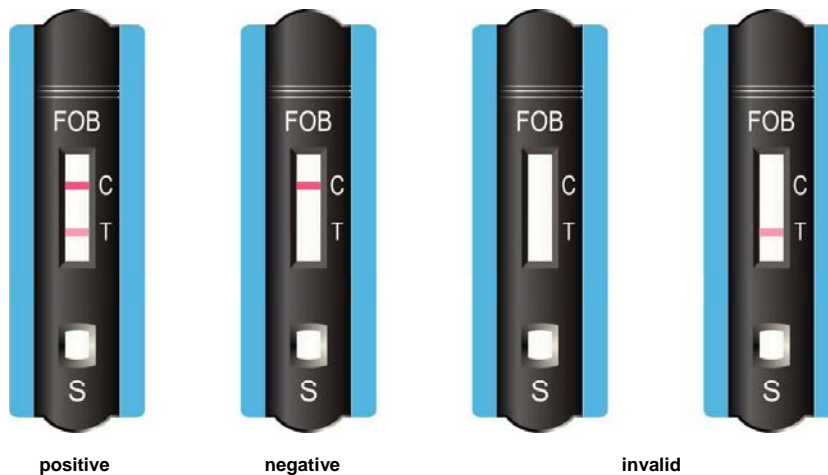
TESTING PROCEDURE

1. Bring the extracted sample to room temperature if it is refrigerated. Then mix the extracted sample well by shaking the sample collection device a few times.
2. Remove the test cassette from the foil pouch, and place it on a flat, dry surface.
3. If the stool sample is refrigerated, then bring the sample collection device to room temperature. Then shake the device several times.
4. Hold the sample collection device so that the device tip faces up, then break off the tip of the collection device. Squeeze 3 drops of the extracted sample into each sample well.
5. As the test kit begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
6. Interpret test results at 10 minutes.

CAUTION: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

- Coloured line will appear at the section of the result window distant from the sample well to show that the test is working properly. This line is the control line ("C" line).
- The section of the result window close to the sample well indicate the test line ("T" line).



Positive Result: The presence of two coloured lines ("C" and "T" lines) in the result window, no matter how faint the "T" line is and no matter which line appears first, indicates a positive result.

Negative Result: The presence of only one purple coloured ("C") line in the result window indicates a negative result.

Invalid Result: If after performing the test no purple coloured line is visible within the result window, the test is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 10 minutes. Interpreting test results after 15 minutes, the sensitivity of the test will be higher.

LIMITATIONS OF THE TEST

1. The FOB test is only intended for the detection of human haemoglobin in faeces.
2. As with other FOB test, results obtained by this FOB test should not be considered as conclusive evidence of the presence or absence of human haemoglobin in faeces. This FOB test is used for preliminary screening only. It is not intended to replace other diagnostic procedures or tests.
3. The presence of blood in stools may be other than colorectal bleeding, such as haemorrhoids, blood in urine or stomach irritations. If a positive result is obtained, additional diagnostic procedures should be performed to determine the cause and source of the occult blood in the fecal specimen.
4. Negative results do not exclude bleeding since it can be intermittent. False negative results may occur when occult blood is not evenly distributed throughout the bowel movement and faecal formation.
5. Some colorectal polyps and colorectal cancers may bleed intermittently or not at all at early stages.

Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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QUALITY CONTROL

Internal Quality Control: A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External Quality Control: Operators should always follow the proper regulatory guidelines to running of external quality controls, such as external negative and positive controls.

Sensitivity: One hundred human haemoglobin free faeces extraction specimens collected in-house were divided into five groups. Thus, each group had 20 specimens. The five groups of faecal extraction specimens were spiked with human haemoglobin for five different concentrations respectively: 0, 5, 25, 50, 3000 ng of human haemoglobin per ml. The specimens were blind labelled and tested with this Faecal Occult Blood Rapid Test at three Physician's Office Laboratories (POL) and a Reference laboratory (RL).



The results obtained from POL have an average 98.1% agreement with the expected results. The results obtained from RL are in agreement by 98.7% with the expected results.


Specificity: This Faecal Occult Blood Rapid Test is specific to human haemoglobin. The following substances were spiked in both positive and negative specimens. They did not interfere the results.

Substance	Concentration (µg/ml)
Bovine Hb	100
Fish Hb	100
Chicken Hb	100
Horse Hb	100
Sheep Hb	100
Broccoli	Extraction
Cantaloupe	Extraction
Horseradish	Extraction
Tulip	Extraction
Cauliflower	Extraction
Vitamin C	Dietary supplement
Iron	Dietary supplement

REFERENCES

1. Bahrt KM, Korman LY, and Nashel DJ, "Significance of a Positive Test for Occult Blood in Stools of Patients Taking Anti-inflammatory Drugs," *Arch Intern Med*, 1984, 144:2165-6.
2. Blebea J and McPherson RA, "False-Positive Guaiac Testing With Iodine," *Arch Pathol Lab Med*, 1985, 109:437-40.
3. Block GE, "Colon Cancer: Diagnosis and Prognosis in the Elderly," *Geriatrics*, 1989, 44(5):45-7, 52-3.
4. Doyle AC, "A Study in Scarlet," Philadelphia, PA: JB Lippincott Co, 1902.
5. Fleischer DE, Goldberg SB, Browning TH, et al, "Detection and Surveillance of Colorectal Cancer," *JAMA*, 1989, 261(4):580-5.

 Manufacturer	 Contents sufficient for <n> tests
 For in vitro diagnostic use only	 Lot. no.
 For single use only	 Expiration date
 Read instructions for use	 Store at

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