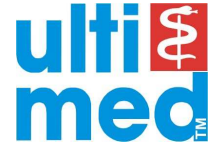
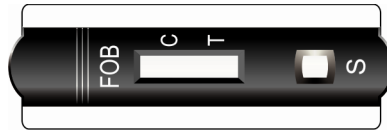


# Early colorectal cancer diagnosis by **FOB Advanced** + Kit 010A210-20



**A rapid, one step test for the qualitative detection of human occult blood in faeces.  
For professional in vitro diagnostic use only.**



## INTENDED USE

The ulti med FOB (faecal occult blood) test cassette is a simple, direct binding immunoassay for the rapid and qualitative detection of human haemoglobin in faeces. This test is used to obtain a visual, qualitative result and is intended for professional in vitro diagnostic use only.

## SUMMARY

The presence of faecal occult blood in the stool is associated with gastrointestinal disorders that may lead to colorectal cancer if not treated. Early diagnosis by FOB screening has been shown to significantly reduce mortality in colorectal cancer. The assay is designed to detect lower levels of colorectal bleeding than other detection methods. In addition, the accuracy of the test is not affected by interfering substances, and dietary restriction is not necessary.

## PRINCIPLE

The test principle is an immunochromatographic sandwich method, which employs two specific monoclonal antibodies to selectively identify haemoglobin in test samples. The results are very specific, and easier to interpret than those of guaiac-based tests. The sensitivity is very high with the ability to detect 40 ng/ml of human haemoglobin in faeces.

## SPECIMEN COLLECTION AND PREPARATION

Collect stool sample by using the special sample collection device provided. First, unscrew the top of the sample collection device, take out the sample collection stick, and collect the sample by dipping the stick into 3 different places of the stool sample. Then, put the sample collection stick back in the sample collection device and screw together tightly.

The stool specimen is to be collected with the stool collection unit. You will find the corresponding instructions of use on the stool collection unit. Important: The stool specimen should not get in contact with water from the toilet or urine. This could adversely affect the test result.

The stool sample dissolved in the buffer solution can be stored at ambient temperature for 14 days and for up to one month at 2-8°C. Stir and bring the specimen to room temperature before testing.

## MATERIALS PROVIDED

- 20 Test cassettes
- 20 stool collection tubes (content 1.5 ml Phosphatbuffer solution, pH 7,4) in clip bag
- 20 stool sample collection units
- 20 short instructions for stool sample collection
- 1 package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

## TEST PROCEDURE

Remove the test cassette from its foil pouch by tearing along the notch. Use the test kit as soon as possible.

Shake the sample collection device vigorously several times.

**Leave the white cap tightly closed!**

Hold the sample collection tube so that the tip of the blue cap faces up, and then break off the tip of the blue cap. Squeeze 3 drops of the extracted sample into the sample well (S). Interpret results after 5-10 minutes. Do not interpret after more than 10 minutes.

## INTERPRETATION OF RESULTS

**Negative:** Only one coloured line appears on the control zone. No apparent line on the test zone.

**Positive:** In addition to a pink coloured control line, a distinct pink coloured line will also appear in the test zone. The intensity of colouration is not important. Even faint pink test lines mean a positive result.

**Invalid:** Total absence of colour in both regions or absence of a coloured line in the control (C) region is an indication of procedure error and/or test reagent deterioration.



positive

negative

invalid

#### QUALITY CONTROL

A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls may also be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process. Users should follow the appropriate local guidelines concerning the running of external quality controls.

#### LIMITATIONS

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. The ulti med FOB Test is intended only for the detection of haemoglobin in faeces.
3. Patients with haemorrhoids or menstrual bleeding should not be considered for testing, however they may be tested after such bleeding ceases.
4. Urine and excessive dilution of samples from water from the toilet bowl may cause erroneous results.
5. The ulti med FOB Test is not for use in testing urine, gastric specimens or other body fluids.

#### PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use test kit beyond expiry date.
- Do not use if pouch is damaged.
- The test device must not be reused.
- Keep out of the reach of children.
- Patient specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedures.

#### STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

#### EXPECTED VALUES

The ulti med FOB Test will detect haemoglobin in faeces at levels as low as 40 ng/ml.

#### PERFORMANCE CHARACTERISTICS

##### Sensitivity

This test is sensitive for 40 ng/ml human haemoglobin in stool sample. 100 spiked stool samples with concentrations of 0 ng, 25 ng, 50 ng, 75 ng, 100 ng per millilitre of human haemoglobin were tested. In the presence of human haemoglobin greater than the cut-off concentration, a positive result was shown by two lines (control and test line appeared). A sample with human haemoglobin levels lower than the cut-off concentration caused a negative result whereby only one line (control) appeared. Moreover, two types of abnormal blood (Thalassemia and Sickle Cell) were tested and no false negative issues were raised as results were as expected.

##### INTERFERENCE TESTING / CROSS REACTIVITY

A performance study was completed to investigate the cross reactivity of other species of haemoglobin and tissue extracts on the FOB Test. The haemoglobin species of bovine, equine, pig, rabbit, sheep, fish, chicken, and goat origin was added to the test device and the results as expected. Haemoglobin of the species was added to normal stool extracts at both 0 and 40 ng/ml human haemoglobin and the results were negative and positive respectively. In addition, the study was repeated with tissue extracts of beef, pig, rabbit, sheep, fish, chicken and goat and no cross reactivity was evident. Lastly, toilet water with the presence of various cleaners (enzymatic to chlorax based) was added to test device and results were as expected following the same protocol as above.

##### DIETARY TESTING







A performance study was completed to investigate the interference of dietary substances on the FOB test. Aqueous extracts of raw broccoli, cauliflower, cantaloupe, horseradish, red radish, parsnip, and turnip were added to test device. Also included were dietary iron, vitamin C and horseradish peroxidase. The dietary substance extracts were added to normal stool extracts at both 0 and 40 ng/ml human haemoglobin and the results were as expected. All of the 0 ng/ml haemoglobin samples spiked with interfering substances were negative, while all of the 40 ng/ml haemoglobin spiked samples were positive.


##### COMPARISON TESTING

To establish the sensitivity and specificity of the ulti med FOB Test kit relative to other qualitative FOB tests, 648 clinical samples were studied. Another commercially available qualitative test kit was used to compare with the ulti med FOB Test kit for relative sensitivity and specificity in these stool samples. Only 2 samples were discordant, the agreement was 99.67%.

#### REFERENCES

1. Gorzynski TJ, Krco CJ, David CS., An idiotope expressed on a monoclonal antibody specific for human haemoglobin beta chain and naturally occurring immunoglobulin(s). J Immunogenet. 1985 Dec;12 (6):281-91.
2. Gorzynski TJ, Krco CJ, David CS., The Hb-2d cross-reactive idiotope. A common idiotope expressed by monoclonal and polyclonal antibodies to human haemoglobin. J Immunogenet. 1985 Dec;12(6):267-79.

 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

 ulti med Products (Deutschland) GmbH  
 Reeshoop 1 • 22926 Ahrensburg  
 Telefon: +49 +4102- 80090  
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[www.ultimed.org](http://www.ultimed.org)

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