

Fecal Occult Blood (FOB)

Rapid Card Test for Detection of Human Fecal Occult Blood

Intended Use

This test is used to detect qualitatively the human hemoglobin in human stool samples. This test is an in vitro diagnostic assay for professional use.

General Information

Detection of Fecal Occult Blood is an important diagnostic procedure for assessment of ulcer lesions in gastrointestinal tract. Numerous studies have showed that the test contributed to early diagnosis of colorectal carcinoma and reduced mortality rates.

This test detects human hemoglobin in human stool samples with high specificity and sensitivity, without any dietary restrictions.

Test Principle

This test is based on immunochromatography method. A monoclonal antibody specific to human hemoglobin was stabilized on a membrane. Another monoclonal antibody specific to human hemoglobin was conjugated with colloidal gold particles and was applied on a pad.

Stool sample which is treated with a special solution is applied on the sample pad. If human hemoglobin is present in the sample it binds to the conjugate and forms a complex. This complex is captured by the antibody on the membrane thus a line appears on the test zone. If human hemoglobin is not present in the sample then no line appears on the test zone. The conjugate is also captured by a specific antibody on the control zone and a control line appears no matter there is human hemoglobin in the sample or not.

Kit Content

Test Device
Sample Extraction Tube (with buffer)
Plastic pipettes
Instructions Manual

Storage Conditions

Test devices and tubes can be stored at 2-30°C. They can be used until the expiry date stated on the label provided that the package is unharmed.

Collection and Preparation of the Samples

Stool samples must be taken in a clean container without preservatives, culture media or detergent. The samples can be tested immediately or can be stored at 2-8°C up to 48 hours. If the samples are to be tested after longer period they should be stored at -20°C or below. Freezing and thawing cycles of the samples may negatively affect the results.

Do not use the stool samples if the patient is on menstrual cycle, has haemorrhoids bleeding or has blood in urine. Excess alcohol consumption, aspirin and some other drugs may cause gastrointestinal bleeding. That's why, stool samples collected under these conditions may not be appropriate for testing. However there is no dietary restriction before collecting stool samples.

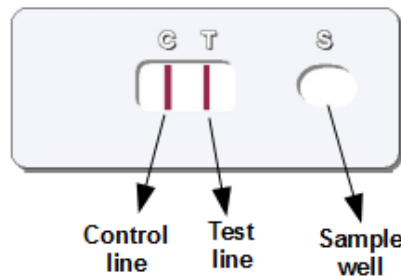
Dip the stick of the tube in different locations of the stool sample and collect a piece approximately 3 mm in diameter. Transfer this sample into the buffer solution and tightly close the cap. Shake well or vortex briefly the tube and then let it settle for a while. Thus a clear brownish/yellowish and almost homogeneous solution is obtained.

Attention: Transferring excess amount of sample into the buffer solution or applying particulate solution on the device may hinder the flow and cause invalid results.



Test Procedure

- 1.Devices, reagents and samples must reach room temperature before beginning the test.
- 2.Place the test device on a level surface and record the patient information on it.
- 3.Break the tip of the tube and holding upside down apply 3 drops (120-150 µl) on the sample well (S).
- 4.Read the result in 5-10 minutes. Do not interpret after 10 minutes.



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Interpretation of Results

Positive Result

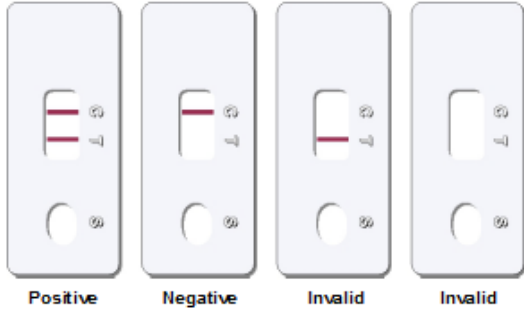
If red/purple lines are visible on both test (T) and control (C) zones then the result is positive. This means that human hemoglobin was detected in the sample.

Negative Result

If there is a red/purple line visible only on the control (C) zone then the result is negative. This means that no human hemoglobin was detected in the sample.

Invalid Result

If there is no red/purple line visible on the control (C) zone then the result is invalid and test should be repeated.



Performance of the Test

Sensitivity and Specificity

This test's analytical sensitivity is 10 ng hHb/ml buffer solution.

The test is specific to human hemoglobin. Stool samples spiked with cow, chicken, goat, pig, horse and rabbit hemoglobins at a concentration of 1 mg/ml gave negative results.

Reproducibility

Negative, weak positive and strong positive samples were tested in 8 copies by 5 different technicians. They all got the same results.

References

1. Young GP, St John DJ, Winawer SJ, Rozen P. Choice of fecal occult blood tests for colorectal cancer screening: recommendations based on performance characteristics in population studies: WHO (World Health Organization) and OMED (World Organization for Digestive Endoscopy) report. Am J Gastroenterol 2002; 97 (10): 2499-2507.
2. Nakama H, Yamamoto M, Kamijo N, Li T, Wei N, Fattah AS, Zhang B. Colonoscopic evaluation of immunochemical fecal occult blood test for detection of colorectal neoplasia. Hepatogastro-enterology 1999; 46(25): 228-31.

Warnings & Precautions

*Read the instructions carefully before using the test.

*This test is designed for in vitro diagnostic use and professional use only.

*Do not use beyond the expiry date indicated on the package.











*Do not use the test if the protective package is damaged.

*Samples may be infectious. Do not pipette by mouth, wear disposable gloves. Avoid splashing or aerosol formation. Wipe spills thoroughly using an appropriate disinfectant.

Dispose all samples, kit components and other test materials in a biohazard container.

*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.

Symbols

-  Test is intended for in vitro diagnostic use only.
-  The product has CE mark.
-  Carefully read the instructions manual.
-  Store at specified temperature.
-  Do not reuse the test.
-  Catalog number of the product
-  LOT number of the product
-  Number of tests in the final package.
-  Do not use if pouch is damaged.
-  Use until the specified date.