RAPID TEST CASSETTE
FOB
Analys FOB test

QUALITATIVE TEST FOR
Human hemoglobin in feces

FOB40TEST-S
FOB40KIT-S
FOBTUB-S

INTENDED USE

Analys FOB test (rapid test cassette) is an immunochromatographic in vitro test for rapid detection of human hemoglobin in feces. The test is intended to facilitate diagnoses of lower gastrointestinal disorders. The test is only intended for professional In Vitro Diagnostic use and clinical considerations and professional judgment must always be added to the analysis, especially in cases where the test results are positive.

SUMMARY AND EXPLANATIONS

The main use of the FOB test is to screen colorectal cancer and major bleeding adenomas. Colorectal cancer is one of the most commonly diagnosed fatal cancers in the United States (Lieberman, 1994; MMWP, 1995). Screening of colorectal cancer increases early detection of the cancer and reduces mortality (Dam et.al, 1995; Miller, 1995; and Lang, 1996).

Previous FOB tests based on the guaiac method require that the patient receive and follow special dietary instructions, otherwise these tests risk giving false positive or negative answers. Analys FOB test is an immunochromatographic in vitro test for the detection of human hemoglobin in faeces, which in turn improves the specificity for the detection of lower GI disorders such as colorectal cancer and adenomas (Frommer et. Al., 1988; St. John et. Al., 1993).

TEST PRINCIPLE

Analys FOB test has been designed to detect human hemoglobin in feces by visually reading color rash on a test plate.

The test plate consists of a membrane coated with anti-human hemoglobin antibodies on a test line, region (T), and with goat anti-mouse antibodies on a control line, region (C).

At the beginning of the membrane there is then a gold-colored anti-hHb colloidal gold conjugate pad.

The patient's stool sample is dissolved in a buffer and the mixed solution is then dropped onto the test plate, where the patient sample mixes with the gold conjugate. The solution is then moved by capillary force to the test region (T). If there is human hemoglobin in the solution, a visible line is formed as the antibodies coated at the test region (T) bind to human Hb. The test result must then be considered positive.

If there is no human hemoglobin in the solution, no visible line is formed in the test field (T) and the test result should therefore be considered negative.

A colored control line should always appear on the membrane at the control zone (C). This shows if the test has worked and that the procedure has gone right. The check mark must always appear regardless of whether the sample contains human hemoglobin or not.

INCLUDED MATERIAL

- 20 individually packaged test plates with test strips pre-coated with antibodies.
- 20 Sampling tubes with 2ml each of 0.1 M Tris-HCl buffered saline, with BSA and 0.02% sodium azide.
- A user manual.

MATERIALS NEEDED, BUT NOT INCLUDED

1. A dry and clean sampling container for the patient's stool sample.
2. Timer / Clock for timing.
3. Some paper to prevent splashes.

STORAGE AND STABILITY

This product should be stored for the intended shelf life in the sealed package, either refrigerated, about +2 to + 8 ° C, or at room temperature, up to + 30 ° C. The product is sensitive to moisture and should always be used immediately when the packaging is broken.

PRECAUTIONS

- For professional diagnostic use only In Vitro.
- Do not use the test equipment after the expiration date.
- Moisture sensitive, do not open the package until the test is to be used.
- Use a new vessel at each test occasion to avoid contamination of the test.
- All patient samples should be treated as infectious.
- Disposal - If the buffer liquid is poured down the drain, be sure to flush the system with water to flush away any residue.
- The patient must be carefully instructed to follow the sampling instructions for the instructions for use. If the patient has menstruation, bleeding hemorrhoids, blood in the urine or has been abnormally hard in the stomach at the time of the test, the test should not be performed but instead postponed.

SAMPLING AND PREPARATIONS

Patients with menstruation, bleeding hemorrhoids or blood in the urine should not be tested during this period.

1. The stool sample is collected in a clean and dry container of plastic or glass, alternatively on a double weight piece of toilet paper.
2. Unscrew the buffer stick from the buffer tube.
3. Used the blue buffer stick to collect the stool sample by randomly sticking it down in several places in the patient sample.
4. Use a soft cloth or paper to wipe off excess stool from the swab before screwing it back into the buffer. Make sure that it is screwed on properly so that leakage does not occur.
5. As the patient's stool sample is now stored in a buffer, the test does not need to be performed directly at the time of sampling but can be stored at +2 to + 30, ° C, for up to 7 days.

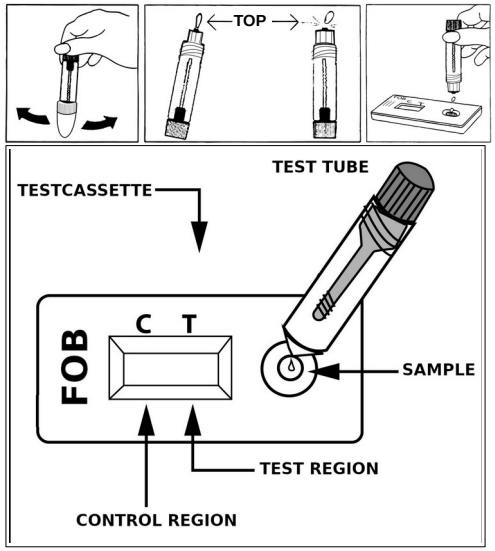
TEST PROCEDURE

QUALITY CONTROL

1. The procedure control is built into the test and consists of a colored band appearing in the control region (C) of the membrane. If this does not appear, the test is considered invalid and must be repeated.
2. A clear background in the test field is to be regarded as an internal negative control. However, when testing with feces, the background, depending on the original color of the stool sample, may become slightly yellowish. This can be accepted as long as it does not adversely affect the ability to interpret the test result. The test is considered invalid if it is not visually possible to read the result.

TEST PERFORMANCE

1. Review the "Sampling" instructions. (Test unit and patient samples should be at room temperature, 20-30 ° C, before testing).
2. Open the package, but not until everything is ready for analysis, and mark the cassette with the patient's ID / Name.
3. Shake the buffer tube so that the stool sample mixes with the extraction liquid in the tube. Unscrew the white protective sleeve and break off the small tip on the buffer tube (use gloves, paper or similar to prevent splashes on the fingers).
4. Hold the buffer tube at a vertical angle to the cassette sample well and then drip 3 drops (120 µl) into the sample cassette sample well.
5. Read the result 5 minutes after the solution has been dropped into the cassette sample well. Strongly positive patient samples can be read earlier. **Never read test results later than after 5 minutes.**
6.

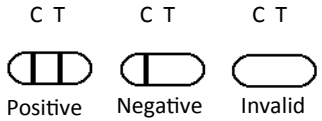


Interpret the result after 5 minutes and never later than after 5 minutes.

INTERPRETATION OF RESULTS

¤ **POSITIVE**: Two clear pink lines appear in the result field, one below C (check line) and the other below T (test line).
A positive result indicates the presence of human hemoglobin in the patient sample.
¤ **NEGATIVE**: Only one pink line is visible, below (C) in the results field. No pink line appears below (T). This response indicates that the patient sample does not contain human hemoglobin.
¤ **INVALID**: The absence of a pink line below (C) in the results field is a sign of a procedural error or that the test reagents may have deteriorated. Repeat the test with a new device and see if a colored control line appears. If the problems persist, contact Salofa Oy, email: feedback@salofa.com.

NOTE that a check line must always appear below the c in the result field, if this does not happen, the test is considered invalid.



LIMITATIONS IN THE PROCEDURE

- The test should only be used for qualitative detection of human hemoglobin in stool samples.
- Not all colorectal haemorrhages are not related to cancer but can include come from hemorrhoids, "hard" stools, etc.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on a single test, but only by a physician after all clinical and laboratory results have been evaluated.
- Negative test results do not rule out that the patient may have bleeding, (colorectal cancer may bleed irregularly or not at all)
- Dilution of the patient sample with urine and water from the toilet bowl may cause incorrect test results.
- Bleeding in the upper part is more difficult to detect because the quality of the hemoglobin is broken down during the passage through the intestine.

PERFORMANCE

A. Sensitivity

- The test is designed to identify concentrations of hemoglobin in faecal solution ≥ 40 ng / ml, (positive result). In some cases, samples containing levels lower than 40 ng / ml may also give positive results.
- The analytical sensitivity from a stool sample is 4.8µg hemoglobin / g faeces
- **Hook or Prozone effect:** Samples containing levels as high as 0.5 mg / ml hemoglobin can still be tested positive. Analys FOB tests have not shown any signs of Hook or Prozone effect up to the maximum detected concentration (500,000 ng / ml). The range for Analys FOB test is between 40ng / ml - 500,000ng / ml.

B. Specificity

- Analys FOB cassette test is specific for human hemoglobin and does not cross-react with hemoglobin from cattle, pigs, rabbits, horses or sheep (tested at concentrations up to 0.5 mg / ml)
- The test also does not cross-react with bilirubin, vitamin C or horse radish peroxidase

C. Clinical specificity

The following non-cancer related factors can cause blood in stool samples

- **Iron**: Supplements containing iron may increase the release of blood in the intestine. Iron itself, does not cross-react with the test.
- **Acetylsalicylic acid:**A common ingredient in many headache medications, and in some blood thinners. Even in healthy people, small amounts of blood are almost always present in stool samples. However, these levels are far below the sensitivity of the test. If a patient takes blood-thinning medications, the tendency to bleed increases, which in turn can result in increased blood in the patient's stool.
- **Varfarin:**Used in blood-thinning preparations such as Varan. These drugs are given for preventive purposes, against heart attacks, thrombosis and stroke. Even in healthy people, small amounts of blood are almost always present in stool samples. However, these levels are far below the sensitivity of the test. If a patient takes blood-thinning medications, the tendency to bleed increases, which in turn can result in an increased amount of blood in the patient's stool.
  Hemorrhoids: Bleeding hemorrhoids can cause blood to be found in the stool that is not related to cancer.
  Menstruation: Small amounts of blood excreted due to menstruation can contaminate the stool sample. Blood is not related to cancer.
  Urine samples: Several diseases can result in blood in the urine. To avoid contamination of urine-related blood, the stool sample should not come into contact with the urine.

A published study conducted at the Shinshu University School of Medicine in Japan, where the cost-effective value of taking multiple samples at different times was evaluated. A clear indication that the relative sensitivity increased markedly with most samples and that the specificity decreased only marginally.

Number of tests	Sensitivity	Specificity
1	58%	96%
2	89%	95%
3	100%	94%

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3. Lieberman, D .; Screening / Early Detection Model for Colorectal Cancer, Why Screen? Cancer Supplement; (1994) 74 (7): 2023-2027.
4. Miller, AB; an Epidemiological Perspective on Cancer Screening; Clinical Biochemistry (1995) 28 (1): 41-48.
5. Ransohoff, DF and Lang, CA; Improving the Feccal Occult-Blood Test; The New England Journal of Medicine; (1996) 334 (3): 189-190.
6. Screening for Colorectal Cancer-United States, 1992-1993, and New Guidelines; Mobility and Mortality Weekly Report; (1995) 45 (5): 107-110.
7. St. John, DJB, et al .; Evaluation of New Occult Blood Test for Detection of Colorectal Neoplasia; Gastroenterology; (1993) 104: 1661-1668.

⚠	NOTE! See instructions for use		Tester per kit		Do not reuse
IVD	For invitations only diagnostics		Use before	REF	REF Catalog #
30°C	Store at rooms temperature, below 30°C	LOT	Lot number		

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