iFOB CARD (IMMUNOCHEMICAL FECAL OCCULT BLOOD)

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

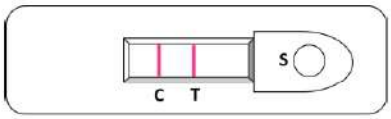
INTENDED USE: Test for qualitative detection of fecal occult blood in human fecal sample.

CLINICAL SIGNIFICANCE

The iFOB (immunochemical Fecal Occult Blood) test is an immunochemical device intended for the qualitative detection of fecal occult blood by laboratories or physicians' offices. It is useful in determining gastrointestinal (GI) bleeding found in a number of gastrointestinal disorders, such as: diverticulitis, colitis, polyps, and colorectal cancer. This test is recommended for use in: (1) routine physical examinations or when hospital patients are first admitted, (2) hospital monitoring for GI bleeding in patients, and (3) screening for colorectal cancer or gastrointestinal bleeding from any source.

PRINCIPLE

The iFOB test is a one-step lateral flow chromatographic immunoassay. The test strip consists of: (1) a burgundy colored conjugate pad containing mouse anti-hHb antibodies conjugated with colloidal gold and (2) a nitrocellulose membrane strip containing a Test line (T-line) and a Control line (C-line). The T-line is coated with anti-hHb antibodies, and the C-line is coated with goat anti-mouse IgG antibodies.



When the correct volume of test specimen is dispensed into the sample well of the device, the test specimen migrates across the test strip. If the concentration of hHb in the specimen is at or above 50 ng hHb/mL or 50µg hHb/g feces, the T-line appears as a visible burgundy line. If the concentration of hHb in the specimen is below the detectable level, no T-line develops.
The C-line is coated with goat anti-mouse antibody, which binds to the conjugated monoclonal antibody, regardless of the presence of hHb in the specimen.

KIT COMPONENTS

Test Device, PBS buffer (1x PBS with 0.02% sodium azide), Sample Dropper and Instructions for Use

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Does not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The specimen used in this assay is feces. Collect specimen in bedpan, a clean cup, or like container.

NOTE: Do not collect specimen if bleeding hemorrhoids, or if menstrual, constipation, or urinary bleeding are present. Do not allow specimen to come in contact with toilet water.

1. Collect patient sample in clean container
2. Add 1 ml PBS Buffer in test tube or collection tube.
3. Randomly pierce the specimen with the Sample Applicator or stick in **at least five (5) different sites.**
4. Insert the Sample applicator or stick into the Collection Tube with 1 ml PBS buffer.
5. Shake the tube to mix the specimen and the PBS buffer.

NOTE: Specimens collected may be stored up to eight (8) days at ambient temperatures below 35°C, six months at 2–8°C or two years at -20°C.

TEST PROCEDURE

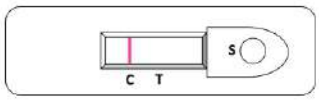
Allow test cassette, specimen, and/or buffer to equilibrate to room temperature (15-30 °C) prior to testing.

1. Remove the Test Cassette from the pouch and place it on a clean, flat, dry, level surface.
2. Put on gloves before performing the following steps.
3. Shake the Collection Tube to mix the specimen and the PBS buffer.
4. Add 4-5 drop (80 - 100 µl) of sample from Collection tube in sample well "S" using the dropper provided.
5. READ RESULTS AT 5–10 MINUTES. Some positive results may be seen earlier.

Note: Do not interpret the result after 10 minutes.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:
One coloured line appears in the control region (C). No apparent coloured line appears in the test region (T).



POSITIVE RESULT:
If both a C-line and a T-line are present, the result is positive. A positive result indicates the level of hHb in the specimen is at or above the detection level.

INVALID TEST:

If no C-line appears within 5 minutes, the result is invalid and the assay should be repeated with a new device.

LIMITATIONS OF THE TEST

The iFOB test is intended only for the detection of human hemoglobin in feces.

1. Results cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source of the occult blood in the feces.
2. A negative result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease.
3. False negative results may occur when occult blood is not uniformly distributed throughout the bowel movement and the formation of a fecal specimen. Repeat testing is recommended if a pathological condition is suspected.

INTERNAL QUALITY CONTROL

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

BIBLIOGRAPHY

1. American Cancer Society, Inc. Cancer Reference Information: Can Colon and Rectum Cancer Be Found Early? [Online] Available: http://www.cancer.org.
2. Allison JB, Takawa IS, Ransom LJ, Adrian AL. A comparison of fecal occult blood tests for colorectal-cancer screening. N Engl J Med 1996; 334:155–159.
3. Saito H. Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J Cancer Res 1996; 87:1011–1024.
4. Recommendations for the Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Centers for Disease Control, August, 1987.
5. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition. U.S.Department of Health and Human Services, CDC, NIH, Washington, DC (1999).

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care: +91-9823388695.
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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE