ACCUCARE™

iFOB Card Test

(Immunochemical Fecal Occult Blood)

A rapid and sensitive test for the qualitative detection of human fecal occult blood

Only for *In vitro diagnostic* use

ORDER INFORMATION

REF	Cont.
FB 10	10 Test
FB 25	25 Test

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 product insert.

1. Store the kit at room temperature 15–30°C, out of direct sunlight. Do not expose kit components to temperatures over 30°C.
2. Kit contents are stable until the expiration date printed on the outer box.
3. Do not freeze.

SPECIMEN COLLECTION & 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.*

ASSAY PROCEDURE

All Test Cassettes and clinical specimens must be at room temperature before beginning the test.

1. Remove the Test Cassette from the pouch and place it on a clean, flat, dry, level surface.

Put on gloves before performing the following steps.

2. Shake the Collection Tube to mix the specimen and the PBS buffer. Add 2-3 drop of sample from Collection tube in sample well "S" using the dropper provided
3 **READ RESULTS AT 5–10 MINUTES.** Some positive results may be seen earlier. **IMPORTANT: Do not read the test results after ten (10) minutes.**

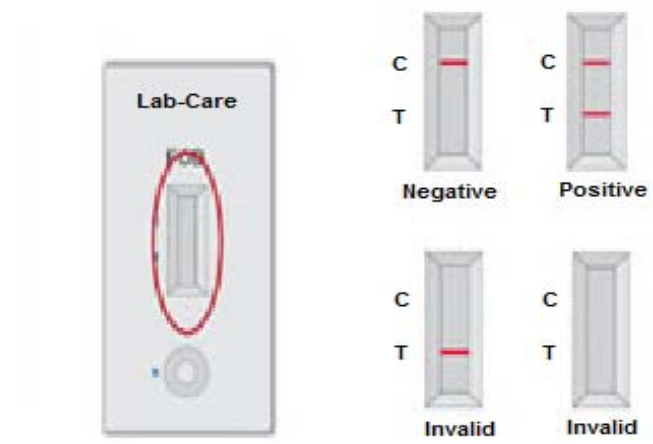
INTERPRETATION OF THE RESULTS

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.

Negative Result: If only the C-line develops in the control region of the test strip, the result is negative.

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

NOTE: *The test line may or may not be present. However, the absence of a control line indicates an invalid test.*



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LIMITATIONS

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.

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).

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