ACCUCARE®
ONE STEP IMMUNOCHEMICAL FECAL OCCULT BLOOD (iFOB) RAPID TEST (Feces)

One step rapid Card/Strip Test for detection of human fecal occult blood

Store at 15-30°C. DO NOT FREEZE.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

REF	Pack Size
FBC10	10 Test
FBC 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

ACCUCARE® ONE STEP iFOB RAPID 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.

CONTENTS

Test Device/Strip
Assay Buffer
Instruction for Use (IFU)
Disposable (Dropper) 25 µl sampling device
Desiccant

Components required but not provided with kit

Sample collection container
Collection tube for PBS buffer
Sample applicator or stick
Stop watch

STORAGE & STABILITY

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. Do not freeze.
3. Do not use beyond the expiration date.
4. Do not use the test device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device/strip.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. ACCUCARE® ONE STEP iFOB RAPID TEST is intended only for the detection of human hemoglobin in feces.
2. 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.
3. 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.
4. 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.

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 Assay 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 Assay 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.*

PROCEDURE FOR DEVICE

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Shake the Collection Tube to mix the specimen and the assay buffer.
4. Place the test device on a clean and flat surface. Carefully dispense 2-3 drops (70 µl) of sample from collection tube in the sample well "S" using the dropper provided.
5. Allow reaction to occur and read the results at 05 minutes. Do not interpret the results after 10 minutes.

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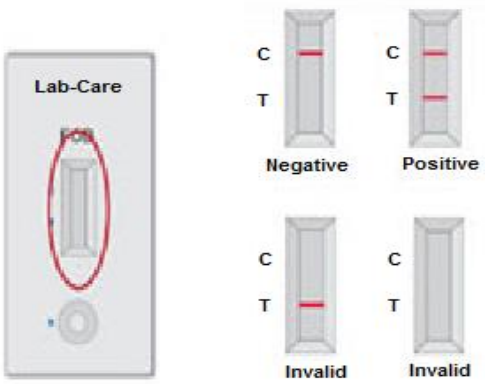
INTERPRETATION OF RESULTS



PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP iFOB RAPID TEST has been evaluated with positive and negative samples and data are as below:

Specimen	Positive	Negative	Sensitivity
Positive	240	00	100 %

Specimen	Positive	Negative	Specificity
Negative	05	295	98.3 %

BIBLIOGRAPHY

1. American Cancer Society, Inc. Cancer Reference Information: Can Colon and Rectum Cancer Be Found Early? [Online] Available: http://www.cancer.org.
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3. Saito H. Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J Cancer Res 1996; 87:1011–1024.
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GLOSSARY OF SYMBOL

	Consult Instruction	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

ISO 13485:2016

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