iFOB Test

Faecal Immunochemical Test (FIT) for the Detection of Faecal Occult Blood in Stool

REF 4194-IFOB-20

INTENDED USE

The iFOB Test is a rapid and convenient faecal immunochemistry test (FIT) for qualitative detection of human haemoglobin in stool samples as an indication for the presence of faecal occult blood (FOB). It is intended for professional use as an aid in diagnosis of colon polyps, colorectal carcinoma, ulcerative colitis, Crohn's disease and GI bleeding. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Faecal occult blood (FOB) refers to blood in the faeces that is not visibly apparent. Presence of human haemoglobin indicates internal bleeding associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease.

The iFOB Test is an antigen capture immune-chromatographic assay, which detects the presence of haemoglobin in faecal samples. Monoclonal antibodies specific against human haemoglobin are (1) conjugated with colloidal gold and deposited on conjugate pad and (2) immobilized in the Test Zone on the nitrocellulose membrane. When a faecal sample is added, the antibody conjugate is rehydrated and the hemoglobin, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible pink-purple coloured band (Test band), indicating a positive result. If haemoglobin is absent in the sample, no pink-purple coloured band will appear in the Test Zone (T).

To serve as an internal process control, a pink-purple coloured control band should always appear at Control Zone (C) after the test is completed. Absence of a coloured control band in the Control Zone is an indication of an invalid result.

The test is specific to detect human haemoglobin and test result is not affected by other animal blood. Therefore, there is no dietary restriction prior to testing.

REAGENT AND MATERIALS SUPPLIED

1. iFOB Test cassette with a desiccant in a sealed pouch
2. Collection Vials with iFOB sample buffer (2 ml/tube) and labels
3. Sample collection paper
4. Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Gloves
2. Clock or timer

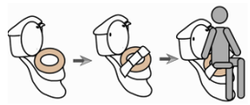
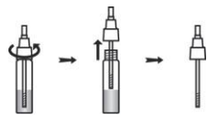
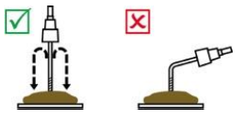
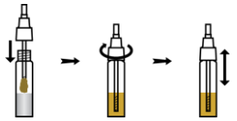
WARNING AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. For single use only, do not reuse.
3. Do not use if the product sealed barrier or its packaging is compromised.
4. Do not use after the expiration date shown on the pouch.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious material and performing the assay.
6. Wash hands thoroughly after finishing the tests.
7. Do not eat, drink or smoke in the area where the specimens or kits are handled.
8. Clean up spills thoroughly with appropriate disinfectants.
9. Handle all specimens as if they contain infectious agents. Observe established precautions against bio-hazards throughout testing procedures.
10. Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
11. Keep out of children's reach.

SPECIMEN COLLECTION AND STORAGE

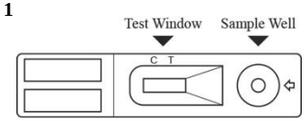
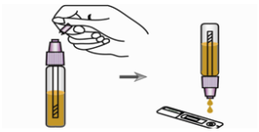
No special patient preparation necessary. If possible, ask patient to urinate first. Prior to defecation, flush the toilet. Pass stool into a fresh bedpan or flushed toilet. Collect a random sample of faeces.

Best results will be obtained if the assay is performed within 6 hours after collecting faecal samples. The collected specimen may be stored in the refrigerator at 2º to 8°C for 3 days.

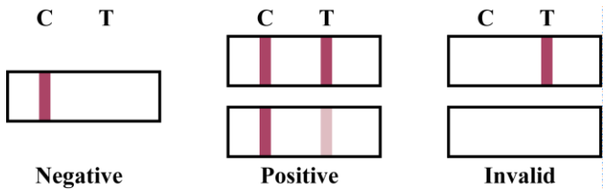
1		Place the sample collection paper on top of the toilet and deposit stool sample.
2		Label vial with patient ID. Unscrew the cap of the Collection Vial and take out specimen collection stick.
3		Stab the specimen collection stick into the faecal specimen in at least 3 different sites (Do not scoop the faecal specimen).
4		Only a small amount of stool is needed. Ensure that only the grooved part at the end of the stick is covered.
5		Insert the specimen collection stick into the Collection Vial and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the buffer.

TEST PROCEDURES

Allow test kit, specimen Collection Vial, specimen, and/or controls to warm up to room temperature (15ºC to 30°C) prior to testing.

1		Remove the test cassette from the sealed pouch and use it as soon as possible. Caution: Do not touch the test window or the membrane inside.
2		Hold the faecal Collection Vial upright and break off the tip with hands. Invert the vial and add four full drops (150 µl) of specimen without air bubbles into the Sample Well of the cassette.
3		Read the result at 15 minutes. NOTE: Specimens with high concentrations of FOB may produce positive result in as little as 1 minute. Confirm negatives at 15 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES

INTERPRETATION OF RESULTS



Negative
A pink-purple coloured band appears only at the control region (C), indicating a negative iFOB result.

Positive
A pink-purple coloured control band (C) and a detectable pink-purple coloured test band (T) appear, indicating a positive iFOB result. Colour intensity of the test band may vary.

Invalid
No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink-purple coloured band in the Control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

KIT STORAGE AND STABILITY

1. Test device in the sealed pouch should be stored at 2ºC to 30ºC. Do not freeze the test device.
2. The Faecal Specimen Collection Device containing the buffer should be stored at 2ºC to 30ºC.
3. The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

1. This product is an *in vitro* diagnostic test designed for professional use only.
2. Humidity and temperature can adversely affect results.
3. The instruction for use of the test should be followed during testing procedures.
4. There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
5. Although the test demonstrate superior accuracy in detecting haemoglobin in faecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, 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.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The iFOB Test can detect human haemoglobin in faecal samples. The lowest detection level or analytical sensitivity of the test for human haemoglobin (hHb), hHb-C, hHb-S is 25 ng/mL in iFOB sample buffer. The test shows no pro-zone effect up to 20 µg hHb/mL.

Specificity:

The iFOB Test is specific to human haemoglobin. No cross reactivity was detected with the following materials using the iFOB test.

SUBSTANCES	CONCENTRATIONS
Human Transferrin	1 mg/mL
Human Myoglobin	1 mg/mL
Porcine Hb	1 mg/mL
Bovine Hb	1 mg/mL
Bovine Serum Albumin	1 mg/mL
Rabbit Hb	1 mg/mL
Porcine Blood	1:100 dilution
Bovine Blood	1:100 dilution
Chicken blood	1:100 dilution
Goat Blood	1:100 dilution
Fish Blood	1:100 dilution
Rabbit Blood	1:100 dilution
E.coli	10^6 cfu/mL
Broccoli	Extracts
Cauliflower	Extracts
Cantaloupe	Extracts
Horseradish	Extracts
Turnip	Extracts

Accuracy:

The diagnostic sensitivity and specificity were determined by comparing performance of iFOB Test and a commercial faecal occult blood test (in triplicates). The clinical studies involved 1002 asymptomatic individuals aged 50-97 in three clinical offices. The test procedures were followed according to manufacturer's Instruction for Use and the test results and conclusions were tabulated as below:

Comparison of iFOB Test (FIT) kits

		Results of commercial kit		Subtotal
		Positive	Negative	
Results of iFOB test (FIT) kit	Positive	104	3	107
	Negative	2	893	895
Subtotal		106	896	1002

Diagnostic sensitivity: 104 / 106 = 98.1%

Diagnostic specificity: 893 / 896 = 99.7%

Total agreement: (104+893) / 1002 = 99.5%

Interference

The following substances and conditions were found to not interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follows:

Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Ascorbic acid	20 mg/dl
Caffeine	20 mg/dl
Gentesic acid	20 mg/dl
Phenylpropanolamine	20 mg/dl
Salicylic acid	20 mg/dl
EDTA	80 mg/dl
Benzoylecgonine	10 mg/dl
Atropine	20 mg/dl
Cannabinol	10 mg/dl
Ethanol	1%
Methanol	1%
Albumin	2,000 mg/dl
Glucose	2,000 mg/dl
Bilirubin	2,000 mg/dl

Reproducibility

The precision was determined by replicate assays of both positive and negative samples with devices from three different production lots. The resultant data indicated no appreciable variation between lots when testing both positive and negative samples with three different lots.

REFERENCES

1. Screening for colorectal cancer using the faecal occult blood test: a critical literature review. European Journal of Oncology Nursing Vol. 5(4) 234-243, 2001.
2. Faecal occult blood test for colorectal cancer screening. Annals of Oncology 13:51-56, 2002.
3. Should organized faecal occult blood test screening be established? Annals of Oncology 13:57-60, 2002.
4. Review article: Fecal occult blood testing for colorectal cancer. Aliment Pharmacol Ther 1998; 12:1-10.

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