TOYO®

INSTRUCTION FOR USE
iFOB (FIT) Test
For hHB (human hemoglogin)
Detection in Feces

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: THHB01

iFOB (FIT) Test detects fecal occult blood in human feces

BACKGROUND INFORMATION
The presence of fecal occult blood in the stool is associated with gastrointestinal disorders such as diverticulitis, polyps, and Crohn's disease, that may lead to colorectal cancer if not treated. Early diagnosis by fecal occult blood screening and treatment of these problems has been shown to significantly reduce mortality from colorectal cancer. Detection of occult blood in feces is a recommended examination method by many organization such as WHO (World Health Organization) for large intestine cancer diagnosis.
Immunochromatographic test methods have superior clinical specificity when compared to a chemical based test (e.g. guaiac) as well as do not required any dietary restrictions.

INTENDED USE
iFOB (FIT) Test is a qualitative immunochromatographic test for detection of human hemoglobin (hHb) in human feces for professional use.

REAGENTS
Mouse monoclonal anti-hemoglobin antibody-A, goat anti-mouse (IgG) polyclonal antibody and monoclonal anti-hemoglobin antibody B conjugated with colloidal gold particles.

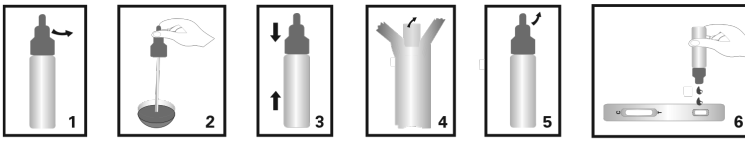
METHOD
iFOB (FIT) Test uses solid-phase immunochromatographic technology for the qualitative detection of hHb in human feces. The test is a two-site immunometric assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect hHb in samples with a high degree of sensitivity. Mouse monoclonal anti-hemoglobin antibody A was immobilized on the test area "T" and goat anti-mouse (IgG) polyclonal antibodies were immobilized on the control area "C" of the nitrocellulose membrane. Monoclonal anti-hemoglobin antibody B conjugated with colloidal gold particles was dried on a conjugate pad.
Sample is introduced from sampling pad. If there is hHb at detectable level in the sample, hHb binds to the mobile monoclonal anti-hemoglobin antibody B conjugated with colloidal gold particles. Together they move to the test area "T". hHB molecules bind to the immobilized mouse monoclonal anti-hemoglobin antibody and as a result of this, hHb molecules that have already bound to mobile monoclonal anti-hemoglobin antibody A (conjugated with colloidal gold particles) become immobilized in the test area "T" thus creating a visible colored signal due to the accumulation of colloidal gold particles in the test area "T" (a colored test line), indicating positive test result. If there is no hHb at detectable level in the sample then sample moves to the test area "T" together with unbound (free) monoclonal anti-hemoglobin antibody B conjugated with colloidal gold particles. Immobilized mouse monoclonal anti-hemoglobin antibody A can not bind to mobilized monoclonal anti-hemoglobin antibody B conjugated with colloidal gold particles, therefore no visible colored signal in test area "T" (no colored test line) can be obtained, indicating negative test result. Regardless of hHb content of the liquid sample monoclonal anti-hemoglobin antibody B conjugated with colloidal gold particles mobile bind immobilized goat anti-mouse (IgG) polyclonal antibodies while liquid sample is passing through the control area "C". Therefore accumulation of colloidal gold particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line should be visible in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS
1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Blood detection can not be realized if the very little amount of blood is not evenly spread across the feces. For this reason, it is recommended that feces sampling should be done from different areas of the feces. In this way sampling possibility of blood in feces increases.
6. Repeating the test every six months is recommended, as there is no continuous bleeding in case of large intestine cancer. Accordingly, detection possibility of periodically bleeding tumor increases.
7. Below are illnesses that cause bleeding, where the test gives a positive result although the patient is not suffering from a large intestine cancer.
- Ruptures in the digestive system
- Oesophageal varices
- Medication that causes gastric irritation e.g. aspirin
- Gastric tumor or malignant tumor
- Meckels diverticulum
- Ulcerative colitis
- Polyps of large intestine
- Hemorrhoids
8. All patient samples should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
9. This test will indicate only the selectively total human hemoglobin (hHb) in the sample, and should not be used as the only basis for the diagnosis.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

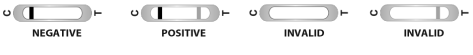
STORAGE
Test device should be kept away from direct sunlight, moisture, heat and radiation sources.Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.
Kit components : Test cassettes, sample collection tubes with dilution buffer, instructions for use.
Additional materials required but not provided : Collection cup and timer.
Additional materials recommended but not provided : Negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION
- The test can be performed using feces samples. Feces samples can be stored at 2 - 8 °C until they are being tested in a period of 3 days after collection if not tested within 6 hours. Sample prepared in the sample collection tube can be stored for 6 months at -20°C if not tested within 1 hour after preparation.
- Sample should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine, false positive test results may be obtained.
- Dietary restrictions are not necessary. Test is a convenient test method that employs anti-human hemoglobin antibodies that causes recognize only human hemoglobin with high sensitivity.

TEST PROCEDURE
1. Open the sampling test tube by turning the lid (Figure 1).
2. Insert and twist the rod into the sample feces in at least 3 different parts of the sample (Figure 2).
3. Insert the rod with the collected sample into the test tube and close it firmly. Shake the sampling test tube well up and low direction for 2 minutes (Figure 3).
   * Please make sure that dilution buffer with fecal sample in tube is homogeneous and it has low solid density .
4. Remove the test kit from its protective aluminum pouch and place the test on a flat surface (Figure 4).
5. Open the cap on the tip of the sampling test tube (Figure 5).
6. Draw 2 drops of sample into sample well of the test cassette (Figure 6).
7. Results should be read within 10 minute as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid .
NOTE: If the extracted sample does not migrate in the test because of the particles, centrifuge the extracted sample in the sample collection tube. Then collect 80 µl supernatant and dispense it to the sample well of a new test device and follow the instruction from step 4.



INTERPRETATION OF RESULTS
Negative : Only one colored band is visible in "C" area.
Positive : Two colored bands are visible in "C" and "T" areas.
Low concentration of hHb may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored band is visible or only one colored band is visible in "T" area; test should be repeated using a new test device.



QUALITY CONTROL
Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION
Cut off value : 10 ng hHb/ml

Sensitivity : 99,9 %
+ Predictive Value : 93 %
Specificity : 97 %
- Predictive Value : 99,9 %

		Reference	
		+ Result	- Result
Test	+ Result	13	1
	- Result	0	30

There is no hook effect (Measurement rage up to 100.000 ng/ml).

Cross Reactivity : There is no any cross reaction interactions with the hemoglobin as follows:
1000 mg/L Cattle Hb
1000 mg/L Sheep Hb
1000 mg/L Horse Hb
1000 mg/L Pig Hb
1000 mg/L Goat Hb
1000 mg/L Rabbit Hb
1000 mg/L Dog Hb

Internal Quality Control: Following substances were used for internal quality control: h Hemoglobin, h Albumin, h Haptoglobin, h Myoglobin, h Transferrin.

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CE

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date