



FOB Fast Test Kit (Immunofluorescence Assay)

IF 1042 for Getein 1100
IF 5042 for Getein 1160
IF 3042 for Getein 1180

Instructions for use

INTENDED USE

FOB Fast Test Kit (Immunofluorescence) is intended for *in vitro* quantitative detection of hemoglobin in human fecal sample. It is used as an adjunctive diagnosis of hemorrhagic lesions. For professional and laboratory use.

SUMMARY

Fecal occult blood (FOB) is a small amount of bleeding in the digestive tract where red blood cells are destroyed by digestion, and there are no abnormal changes in the appearance of the stool that cannot be confirmed by the naked eye or microscope. In the early stage of gastrointestinal malignancies, about 20% of patients may have a positive occult blood test, the positive occult blood rate can exceed 90% in the later stage, and may be persistently positive. Gastrointestinal bleeding and patients with peptic ulcers often have intermittently positive stool occult blood tests. Dysentery, rectal polyps, hemorrhoids, and other bleeding can also lead to an increased presence of red blood cells in the stool, resulting in a positive occult blood test. Therefore, fecal occult blood testing can be used as an important test to detect gastrointestinal bleeding caused by various reasons, and it is a relatively effective method. Currently, the main clinical methods of fecal occult blood test are colloidal gold, Immunofluorescence assay and chemical method.

PRINCIPLE

FOB Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled hemoglobin monoclonal antibody binds with the hemoglobin in sample and forms a marked antigen-antibody complex. This

complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another hemoglobin monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of hemoglobin in sample. Fluorescent signals intensity can be analyzed by applicable device thus the hemoglobin in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
FOB test card*	10 pcs	25 pcs
Sample diluent**	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

* FOB test card

A test card main consists of: Fluorescence latex-labelled hemoglobin monoclonal antibody, hemoglobin monoclonal antibody and polyclonal IgG antibody.

** Sample diluent main consists of: phosphate buffer (20 mmol/L), Na₂S₂O₃ (<0.1%).

Note:

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4-30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

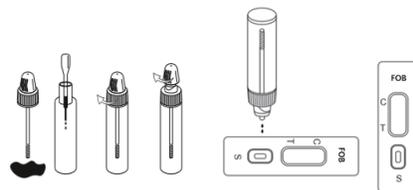
PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch is damaged.

- Do not open pouches until ready to perform the test.
- Do not reuse the test card.
- Do not reuse the sample diluent.
- Handle all samples as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow the instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for fecal sample, other bodily fluids may cause incorrect or inaccurate results.
- Fecal sample should be stored in a clean container and detected immediately after sampling. If testing will be delayed, fecal sample may be stored up to 2 days at 2-8°C or stored at -20°C for 1 year.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles. The proposed sample freeze-thaw is not more than 1 time.
- Sample preparation:
 - Open sample diluent and take out the sample stick, insert it into the fecal sample and then return the fecal sample stick into the tube. Tighten the tube and shake it gently. Repeat the above action 3 times and take different sites of fecal sample and try to avoid obtaining clumps of fecal matter each time.
 - Or use a sample stick to pick 10-50 mg fecal sample, and put into the tube, tighten and shake gently and thoroughly to use. Note: It's recommended to use fresh fecal sample for testing, the sample mixture should be detected within 1 hour.



TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.

- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the "Stool" pattern on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Take out the treated sample mixture, clockwise turn off the cap lid, invert the mixture, discard the first 3 drops, and drip vertically 3 drops (about 100 µL) of the mixture without bubbles to the test card.
- Reaction time: **10 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the "Stool" pattern on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Take out the treated sample mixture, clockwise turn off the cap lid, invert the mixture, discard the first 3 drops, and drip vertically 3 drops (about 100 µL) of the mixture without bubbles to the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**10 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180.

Others: Dilute the sample which concentration is higher than

the upper limit with Sample diluent, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for FOB was determined by testing samples from healthy individuals. The upper limit (95th percentile) of the reference range is 50 ng/mL. It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	25~1000 ng/mL
Limit of Detection	25 ng/mL
Within-Run Precision	≤10%
Between-lot Precision	≤15%

LIMITATIONS

1. For *in vitro* diagnosis only.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
3. Samples containing interferences may influence the results. The table below listed the maximum allowance of these potential interferences.

Interferent	Concentration (Max)
Pig hemoglobin	500 ug/ml
Bovine hemoglobin	500 ug/ml
Chicken hemoglobin	500 ug/ml
Sheep hemoglobin	500 ug/ml
Rabbit Hemoglobin	500 ug/ml
Horseradish peroxidase	2000 ug/ml

REFERENCES

1. Simon JB. Occult blood screening for colorectal carcinoma: a critical review. *Gastroenterology* 1985; 88:820-37
2. Blebea J, Mcpherson R A. False-positive guaiac testing with iodine[J]. *Archives of Pathology & Laboratory Medicine*, 1985, 109(5):437.
3. A J C, A I H. Diagnostic Fecal Occult Blood Testing in

Hospitalized and Emergency Department Patients: Time for Change? [J]. *Laboratory Medicine*, 2018, 49(4):385-392.

4. C H B. Fecal Occult Blood Testing Is Inaccurate as Part of Diagnostic Workup. [J]. *American family physician*, 2020, 102(11):692-692.
5. Özdemir Özlem, Akalın Çağrı, Çınar Hamza. Investigation of Hemogram, Endoscopy, Demographic Properties of Patients Applied by Fecal Occult Blood Test Screening[J]. *Middle Black Sea Journal of Health Science*, 2019, 180-185.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on FOB Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		

Thank you for using FOB Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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