

## For Self - Testing & In-Vitro Diagnostic Use Only

Store at 2°C to 30°C

### OVERVIEW

The number of conditions including colorectal cancer, Crohn's Disease, polyps, hemorrhoids etc. can be a cause of presence of a blood in stool. Detection of fecal occult blood (FOB) makes the diagnosis of possibilities of these conditions without having uncomfortable procedures like endoscopy.

### INTENDED USE

Rapid FOB Test is a rapid chromatographic immunoassay for the qualitative determination of blood in fecal specimen as a marker in the screening of digestive disorders/diseases such as colorectal cancer or Crohn's disease.

This test is for healthcare professional use only.

### PRINCIPLE

The test device consists of a strip with a membrane (NCM), conjugate pad and sample pad. The membrane is pre-coated with Anti-FOB mAb on the test line region of the test. During testing, the stool suspension is prepared as per designed procedure and two drops of suspension are added in the sample well of the device. In case of FOB positive sample, the blood in the specimen reacts with the nanoparticle coated with anti-FOB antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture Ab on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### CONTENTS OF KIT

1. Test Device with desiccant
2. FOB Tube filled with dilution buffer.
3. Package Insert.

### OPTIONAL MATERIAL REQUIRED

1. Stopwatch

### PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 2°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

### WARNINGS

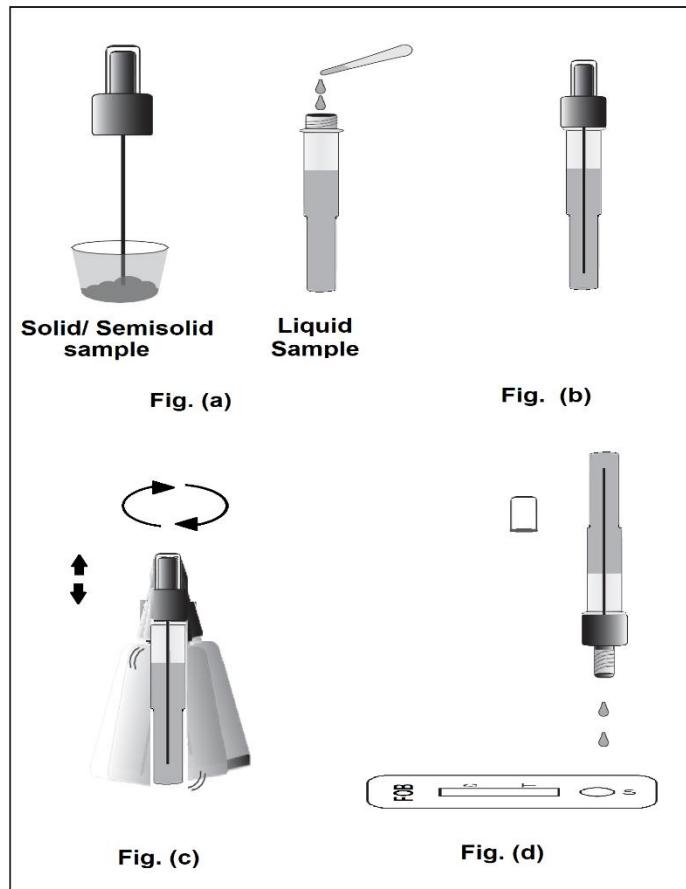
1. Do not reuse the test or test components.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the used test and kit components hygienically in biohazard waste.
5. Do not touch the membrane.
6. Treat the samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or consequential arising out for related to an incorrect diagnosis.

### SPECIMEN COLLECTION

1. Label the FOB tube with the patient identity.
2. Unscrew the cap of the tube and dip the sampling stick to collect a loopful suspension of stool specimen and put into the tube (Fig. a).
3. In case of liquid stool, use plastic dropper to transfer two drops of stool into the tube and put into the tube (Fig. b).
4. Tightly recap the tube. Shake the tube to mix the content.
5. Use this suspension as a sample for testing within two hours.
6. This suspension can be stored up to 2 days at 2 to 8 °C for testing.

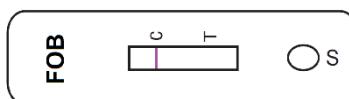
### TEST PROCEDURE

1. Bring all kit components and samples to room temperature (20 to 30 °C) before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity.
4. Keep the device on plain surface & add two drops (Approx. 60 µl) prepared sample in sample well 'S' by piercing the cap of FOB tube in which the sample is collected.
5. Start the timer.
6. Read the result at 15 minutes. Do not read the result after 20 minutes.

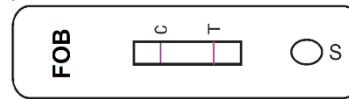


### INTERPRETATION OF RESULTS

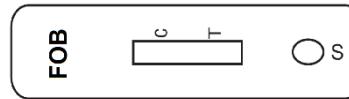
**Negative:** If colored line appears at control region 'C' & no colored band appears at test region T, then sample is negative for FOB.



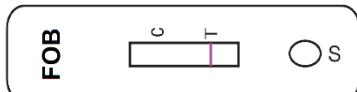
**Positive:** A distinct clearly visible colored line appears at control region 'C' and at the test region 'T', then specimen is positive for FOB.



**Invalid:** Test should be considered invalid and repeat the test using fresh test if a. No line appears at control side 'C' and line appears only at test side 'T'.



b. No line appears at control side 'C' and test side 'T'.



#### Note:

The intensity of the colored line in the test region (T) will vary depending on the levels of FOB. However, neither the quantitative value nor the rate of increase in level of FOB can be determined by this qualitative test. Positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 15 minutes.

#### PERFORMANCE CHARACTERISTICS

##### INTERNAL EVALUATION

Total 190 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (60/60) and relative specificity was found 100% (125/125).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with H. pylori, S. typhi & cholera positive samples.

Lowest detection limit: 5.0 ng/ml

Sample	LH Test		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	60	0	60	0	100	-	100	-
Negative	0	125	0	125	-	100	-	100
Cross reactivity	0	6	0	6	No cross reactivity observed			
Total	60	131	60	131	-			

##### EXTERNAL EVALUATION

The product is evaluated by NABL approved laboratory. 100 % sensitivity and 100 % specificity were found in external evaluation.

#### LIMITATIONS

- As with all diagnostic tests, the test result must always be correlated with clinical findings.
- The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
- Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.
- The test is limited to the determination of FOB; Other clinically available tests are required if questionable results are obtained. 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.

#### DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

<b>IVD</b>	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
<b>LOT</b>	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use



#### MANUFACTURED BY

ImmunoScience India Private Limited

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