

FOB Rapid Test Kit

Instruction for use

【Product Name】 FOB Rapid Test Kit

【REF】 A10033001B, A10033001A, A10033001C, A10033001D, A10033001E

【Specification】 1 test/kit, 2 tests/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The FOB Rapid Test Kit is a colloidal gold immunochromatography intended for the qualitative detection of Hemoglobin (Hb) in human fecal sample. The test is used to obtain a visual, qualitative result and is intend for healthcare professional use.

【Summary】

The detection of fecal occult blood is important for the diagnosis of disease that results in gastrointestinal bleeding and to screen for colorectal cancers and large adenomas that bleed. Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality.

【Test Principle】

The FOB raid Test is a chromatographic immunoassay for the qualitative determination of Hemoglobin (Hb) in human fecal sample. When fecal sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-Hb conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-Hb that is coated on the test region. If Hb is present, the result is the formation of a colored band in the test region. If there is no Hb in the sample the area will remain colorless. The sample continues to move to the control area and forms a pink color, indicating the test is working and the result is valid.

【Main Components】

Materials Provided:

Material \ Specification	1 test/kit	2 tests/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	2	5	10	25
Sample Diluent	1	2	5	10	25
Instruction for Use	1	1	1	1	1

Materials Required but Not Provided:

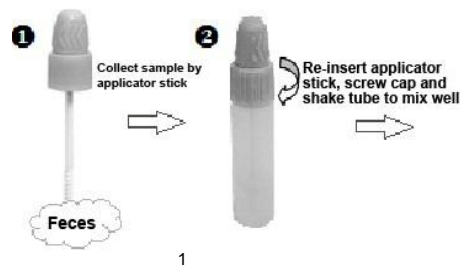
- 1.Timer
- 2.Pipette
- 3.Biohazard disposal container
- 4.Any necessary personal protective equipment

【Storage Conditions and Validity】

- 1.This product should be stored in a dark and dry place at 2~30°C.The validity period of the kit is 24 months.
- 2.After unpacking the aluminum foil bag of the test cassette, It should be used in the specified environment (Temperature 2-35°C, Humidity 40%-90%) within 1 hour.
- 3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handling】

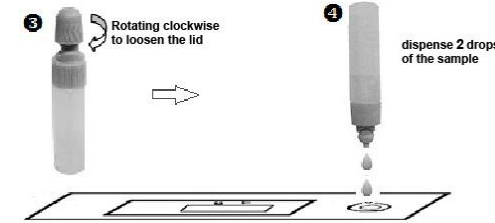
1. This kit is used to detect human feces samples. Other samples may not get accurate results.
2. Remove the applicator stick from the sample collection tube. Insert and turn the stick into the feces sample 5-6 times at different sites (fully covering the spiral groove on the applicator stick).
3. Re-insert the applicator stick into the sample collection tube, screw the cap and shake the tube vigorously to mix the sample well.
4. Testing should be performed immediately after the feces have been collected. If the feces cannot be processed immediately, it may be held at 2 ~ 8 °C for up to 48 hours.



【Test Method】

Note: Please read the Instruction for Use carefully before use. The test should be operated in room temperature.

- 1.Read package insert carefully before testing. Bring all test cassettes and samples to room temperature (10-30°C). Do not open pouches until ready to perform the assay.
- 2.Remove the test cassette from the foil pouch and place on a clean dry surface.
- 3.Rotating clockwise to loosen the lid of sample collection tube cap.
- 4.Invert the sample collection tube and dispense 2 drops of sample which has been mixed evenly and without bubble into the sample well on the cassette, start timing.
- 5.Interpret the test results at 5-10 minutes. Do not interpret the results after 10 minutes.

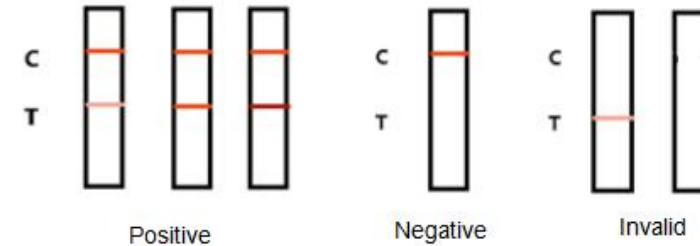


【Interpretation of Test Results】

Positive(+):There is coloration on line C,and a colored line appeared T line.

Negative(-): There is coloration on line C only showing as following picture

Invalid: There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.



【Reporting of Results】

Positive test:

If any Positive, there is currently a suspicion of disease of gastrointestinal bleeding.

Negative test:

Negative test results do not preclude the suspicion of disease and should not be used as the sole basis for treatment or other patient management decisions. If necessary, it is recommended that these results be confirmed by other methods.

Invalid:

If the control line C is not visible, the result is invalid. An invalid result may have been caused by the incorrect execution of the test. Please perform a new test with a new sample and a new test cassette. If the result is invalid again, you should consult a doctor or a test center.

【Limitation of The Test】

1. The kit can be used for the detection of human feces samples.The reliability of the determination of this substance in other types of samples has not been fully confirmed.
2. The kit will only indicate the presence of Hemoglobin (Hb) in the specimen and should not be used as the sole criteria for the diagnosis of disease of gastrointestinal.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist additional testing using other clinical methods is recommended.
5. Other factors may interfere with Anbio FOB Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in feces specimens.

【Performance Characteristics】

1. Sensitivity and Specificity

The FOB rapid test can detect Hemoglobin in human fecal sample with concentration of 0.1µg/ml or greater. In a comparison of the Anbio FOB test versus a leading commercial FOB rapid test, results gave sensitivity of 100%, a specificity of 99.01, and a total agreement of 99.36%.

FOB rapid Test Kit	FOB test		
	Positive	Negative	Total
Positive	56(a)	1(b)	57(a+b)
Negative	0(c)	100(d)	100(c+d)
Total	56(a+c)	101(b+d)	157(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	100.00%	93.63%~100.00%	
Clinical specificity	99.01%	94.61%~99.98%	
Total coincidence rate	99.36%	96.50%~99.98%	

2. Interference testing







No interference was found with any of the substances at the following concentrations:











substance	concentration
Swine hemoglobin	1mg/ml
Chicken hemoglobin	1 mg/ml
Bovine hemoglobin	1 mg/ml
Rabbit hemoglobin	1 mg/ml
Dog hemoglobin	1 mg/ml
Sheep hemoglobin	1 mg/ml
HRP	2 mg/ml

【Limitations】

1. The assay should be performed in normal room temperature.
2. Test cassette should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.
3. The test cassette may be stored under room temperature and dry condition. If refrigerated, the strips should be brought to room temperature before testing.
4. Although the test is very accurate, a low incidence of false results can occur.
5. If negative or questionable results are obtained, the test should be repeated on a fresh fecal sample using a new device.
6. A negative result does not rule out FOB because the Hemoglobin may be absent at the time the specimen is taken or may not be present in sufficient quality to be detected at early stage.
7. 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.


【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer

	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

【Basic Information】

 Anbio (Xiamen) Biotechnology Co.,Ltd.
 Add: No.2016,Wengjiao West Road, Xinyang Street, Haicang District, Xiamen,Fujian,China.
 Tel:+86-592-6312399,Email:info@anbio.com

 Lotus NL B.V.
 Add:Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
 Email: peter@lotusnl.com

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