



Fecal Occult Blood / Transferrin Combo Test Kit Package Insert

【PRODUCT NAME】

Fecal Occult Blood / Transferrin Combo Test Kit

【PACKAGE SPECIFICATION】

1 test/kit.

【INTENDED USE】

This product is used for in-vitro test for the qualitative detection of human occult blood in feces by (Hb) and (TRF) .

Hidden blood in the feces, also known as Fecal Occult Blood (FOB), or Occult Blood, is a important warning sign for gastrointestinal problems. Feces Occult Blood are not visible to naked eye, but by using FOB/TRF combo colloidal gold test method, it can qualitatively detect low levels of Fecal Occult Blood rapidly and accurately.

FOB Test is a very important test method to test GI bleeding and malignant tumor of alimentary canal. It is also a regular screening test indicator of early stage tumor of alimentary canal. It is applicable to Colorectal Cancer noninvasive screening.

【PRINCIPLE】

Applying colloidal gold test technology, the FOB Rapid Test uses immunochemical methodology to detect (Hb) and (TRF) levels in human feces sample.

When the stool sample contains antigens of Hb and TRF, it will react with the colloidal gold-antibody-Coupling, then become colloidal gold antibody conjugate. The colloidal gold antibody conjugate migrates upward on the membrane chromatographically by capillary action to react with pre-coated Hb-antibody and TRF-antibody (both mouse-anti-human), then combined to a

mixture, which will generate a colored Test line (T1/T2).

If the sample only has one of Hb or TRF, the testing region will only generate one colored Test line (T1 or T2); if the sample does not have Hb or TRF, the testing region will not generate any colored Test line.

Colloidal gold-antibody-Coupling migrates upward on the membrane chromatographically to the control line (C). The control line should generate a red colored line when testing. This indicates the test strip is working properly.

【MATERIALS】

Buffer Cap (contains buffer liquid inside), sampler (contains test strip), and user instruction guide.

Test strip material: a)colloidal gold pad b)nitrocellulose filter membrane c)PVC pad, sample pad, and water-absorb pad.

Note: The sampler is only used for one person's sample. Stool-sample collecting paper is enclosed in the kit.

【STORAGE AND STABILITY】

The kit should be stored at room temperature or refrigerated (2-30°C), keep dry, avoid strong and direct light.

Term of validity: 18 months.

The sampler should be used within 1 hour after opening the sealing of aluminum foil.

Product lot number,and expire date are printed on the label.

【SAMPLING REQUIREMENT】

Use the sampler probe scraping back and forth on the surface of the stool.

It is recommended to collect fresh stool. Sample shall not be collected in menstruation or hematuria.

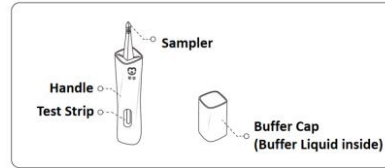
【OPERATION STEPS】

Please read this User Instruction Guide carefully, and operate the test according

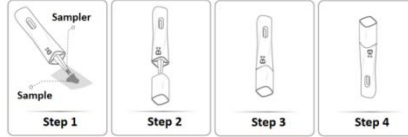
to the Guide strictly.

1.Open the package, take out the sampler and buffer cap, check the sealing film and test strip are intact. Put the buffer cap on the table in upward direction.

2.Use the sampler probe scraping back and forth on the surface of the stool.



3.Insert the sampler (with sample already adhered on the sampler) into the buffer cap at the downward direction, press it firmly; make sure the sampler and buffer cap are fully locked, then wait for 10 seconds; turn the sampler up-side-down, and wait for 3-10 minutes, read the result.



【VALUE OF POSITIVE/NEGATIVE RESULT】

This reagent could detect (Hb) in samples at level no lower than 0.2µg/mL, and TRF no lower than 40ng/mL

【INTERPRETATION OF RESULTS】

TRF positive: Two lines appear--C Line (control line) and T1 Line (Test Line)

FOB positive: Two lines appear--C Line (control line) and T2 Line (Test Line)

TRF/FOB both positive: three lines appear--C Line, T1 Line and T2 Line

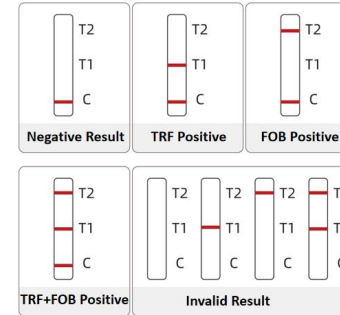
Negative Result: One line appear--C Line (control line)

Invalid Result:

As long as the C Line (control line) does not appear, the result is invalid.

Sample volume insufficiency or other mis-operation can lead the result which the C Line is unable to appear.

(In this case, you need to use a new test kit to redo the test.)



【LIMITATIONS】

1. The Zoan Test is for in vitro diagnostic use only.

2. The FOB/TRF combo test will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.

3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician, such as symptoms, medical history etc.

4. Other clinical tests are required if questionable results are obtained.

【PERFORMANCE CHARACTERISTICS】

1.Appearance: The handle is sealed evenly, without obvious gap; the sealing film is intact

2.Width of Membrane: Width≥2.5mm

3.Liquid moving speed: speed ≥ 10mm/min

4.Sensitivity: FOB≤0.2µg/mL; TRF ≤ 40ng/mL

5.Consistency rate: 100%

6.Repetitiveness:

Test FOB positive reference and Hb negative reference for 10 times respectively, the test line appears steady

and clear;

Test TRF positive reference and TRF negative reference for 10 times respectively, the test line appears steady and clear;

7.Difference between batches: Take 10 test kits randomly from three different batches, test to FOB positive reference /TRF reference, the results of are all steady and clear.

【NOTICE】

1.Zoan reagent is an in-vitro diagnosis reagent of one-time use. Do not reuse it. Do not use products which are expired.

2.The result will not be accurate to people who are in menstruation, hemorrhoids hemorrhage, hematuria period.

【SYMBOLS USED ON LABELS】

Symbol	Usage
	Use-By date
	Batch code
	Manufacturer
	Keep Away from Sunlight
	Temperature Limit
	In Vitro Diagnostic Medical device
	Authorized Representative in the European Community
	CE Mark
	Do not use if package is damaged
	Date of manufacture

【BASIC INFO】

Manufacturer: Shijiazhuang Hipro Biotechnology Corp, No.3 Building,Fangyi Tech-park, 313 zhuijiang Rd, Shijiazhuang city, P.R.China
Tel:086-400-0191-606
Version:1.0

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Fecal Occult Blood / Transferrin Combo Test Kit

User Instruction Guide

Used for samples of fresh stool

Only for in-vitro diagnosis (IVD) test



【Procedure of sample collecting】

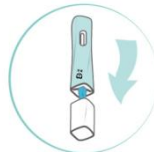
1. Use the sample-collecting-paper to collect the sample of stool, making sure the **sample should not be touched by water**;
2. Use the sampler probe scraping back and forth on the surface of the stool.

【Attention】

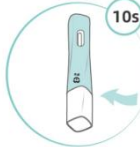
1. If the samples are collected with water, it will dilute the sample, therefore lead to inaccurate result.
2. Sample-collecting-paper could be resolved with water flushing.

③ Start test

1. Insert the sampler (with sample already adhered on the sampler) into the buffer cap **at the downward direction**, then press it firmly.



2. Make sure the sampler and buffer cap are fully locked, **wait for 10 seconds**.



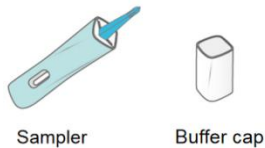
3. Turn the sampler up-side-down, wait for 3-10 minutes, then read the result



① Preparation before test

1. Open the package, take out the sample-collecting-paper and aluminum foil bag.

2. Open the aluminum foil bag, take out the sampler and buffer cap.



3. Put the buffer cap on the table, double check if the sealing film (in the buffer cap) and test strip (in the sampler) are intact.

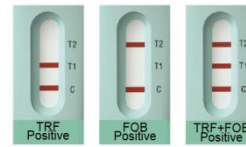
② Collection of sample

【Requirement to Sample Collecting】

1. Sample stool should be fresh;
2. Sample shall not be collected in condition of menstruation or hematuria.

④ Result interpretation

Positive result



TRF positive: C Line and T1 Line
 FOB positive: C Line and T2 Line
 TRF/FOB both positive: Three Lines

If your test result is positive, please double check if your sample has interference material, such as menstruation, hemorrhoids hemorrhage, hematuria etc.

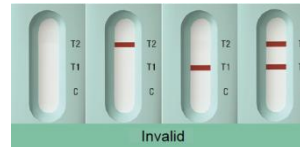
If it is confirmed there was no above interference factor, it is suggested to go to your local medical institution for further diagnosis.

Negative Result :



One line appear--C Line (control line)

Invalid Result



In case the C Line (control line) does not appear, the result is invalid.

Sample volume insufficiency or other incorrect-operation could lead to invalid result. In this case, you need to use a new test kit for re-test.

Disposal of test kit

Zoan's reagent is in-vitro diagnosis reagent for **one-time use only**. Do not reuse it. Do not use expired products. After testing, discard the waste material in trash.

⑤ Q&A

Q: What is Feces Occult Blood?

A: We commonly think if we bleed, we can see it by our eyes.

In fact, there is one kind of bleeding that is "silent", which cannot be seen by our naked eye. This is "occult blood".

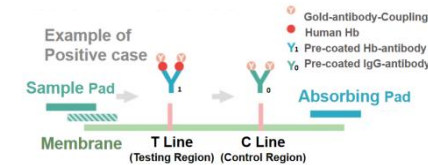
Feces Occult blood cannot be seen by naked eye, nor by microscope, but it can be tested and identified by some scientific testing method.

Q: What are potential diseases if there is feces occult blood?

A: Cancer of the esophagus, colorectal cancer, internal hemorrhoids, intestinal polyp, gastric and duodenal ulcer, intestinal tuberculosis, hookworm disease, HFRS, amoebic dysentery etc.

Q: What is the principle of Feces Occult Blood Test?

A: Applying colloidal gold testing technology, the FOB Rapid Test uses immunochemical methodology to detect (Hb) levels in human feces sample.



When the stool sample contains antigens of Hb and TRF, it will react with the colloidal gold-antibody-Coupling, then become colloidal gold antibody conjugate. The colloidal gold antibody conjugate migrates upward on the membrane chromatographically by capillary action to react with pre-coated Hb-antibody and TRF-antibody (both mouse-anti-human), then combined to a mixture, which will generate a colored Test line (T1/T2).

If the sample only has one of Hb or TRF, the testing region will only generate one colored Test line (T1 or T2); if the sample does not have Hb or TRF, the testing region will not generate any colored Test line.

Colloidal gold-antibody-Coupling migrates upward on the membrane chromatographically to the control line region, it will react with pre-coated IgG-antibody, then combined to a mixture, which will generate a colored Control line

(C). The control line should generate a red colored line when testing. This indicates the test strip is working properly.

Q: What is the purpose of TRF Test?

A: TRF (Transferrin) is in human blood. In feces occult blood, TRF can be found (tested) by TRF testing method. In human feces blood, TRF is actually more steady than Hg. Therefore, combined test of FOB/TRF can test more accurately, which is very important in feces occult blood test.

Q: I have feces blood which is seen by my eyes, but why do I have a negative result?

A: Feces occult blood test is designed for occult blood which cannot be seen by naked eye. When there is too much volume of blood, the level of antigen (Hg) are beyond HB antibody level - this will cause the inaccuracy of result.

Q: During operation of test, is there a high risk of leaking or peculiar smell?

A: No. The sampler is designed fully sealed. This can allow the extra liquid to go to the waste buffer thoroughly. In addition, Zoan also has function of odor removal, which can avoid peculiar smell.

Q: Who should take regular FOB test?

- A: Following group of people are highly recommended to take FOB tests regularly
1. Chronic Diarrhea: aggregation of diarrhea for more than 3 months in last 2 years, diarrhea duration more than 1 week
 2. Chronic Constipation: aggregation of Constipation for more than 2 months in last 2 years
 3. First-degree relative (parents, brothers and sisters, childrens) has diagnosed colorectal cancer
 4. Age more than 45

Q: What should I do if I get an invalid result?

A: Manual operating error may cause invalid result. It is suggested to use a new one to re-test.