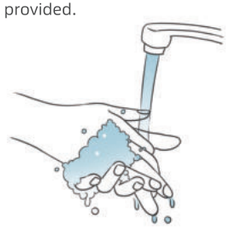
ZOAN™

Feces Occult Blood / Transferrin Combo Test Kit

User Instruction Guide

【PREPARATION】

1. Follow the below steps for preparation.
2. Ensure the test kit is at room temperature for at least 30 minutes prior to use.
3. A timing device (clock, phone or timer) is required but not provided.



Step 1

- 1a Wash hands before and after the test, either using soap and water or hand sanitizer.
- 1b Make sure hands are dry before starting.

Step 2

- Read the instructions for use carefully before using the ZOAN™ FOB/TRF test kit.

Step 3

- 3a Check the expiration date on the label of foil pouch and extraction buffer cap.
- 3b Do not use if it is beyond expiration date or if it is damaged.

Step 4

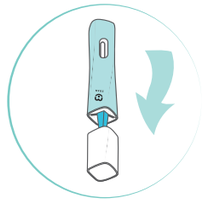
- 4a Open the test device foil pouch.
- 4b Place the test device and extraction buffer cap on a dry and clean surface.
- 4c Check the result window and specimen well on the test device.

【OPERATION PROCEDURE】

Sample stool should be fresh

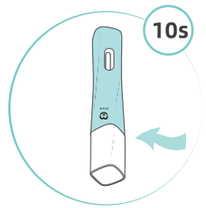
Step 5

- 5a Put the sample-cllecting-paper in the toilet seat. The sample-cllecting-paper should not touch water;
- 5b Deposit stool sample on the sample-cllecting-paper. The sample should not touch any water;
- 5c Use the test device (tip part) to fully collect sample on the clean collection paper, back and forth ;



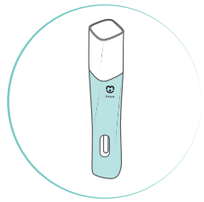
Step 6

- 6a Insert the test device into the extraction buffer cap downward;



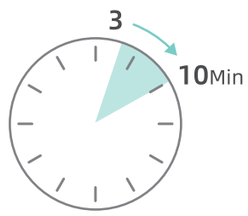
Step 7

- 7a Make sure the test device and extraction buffer cap are fully screwed so that the sample can be completely extracted;
- 7b Wait for 10 seconds;



Step 8

- 8a Put the test device vertically on the flat surface with extraction buffer cap up;



Step 9

- 9a Wait for 3-10 minutes to read the results ;
- 9b Do not read results after 10 minutes .

【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".

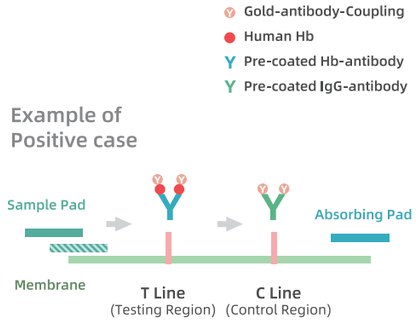
Feces occult blood cannot be seen by naked eye, nor by microscope , but it can be tested and identified by some scientific testing method.

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

A:Cancer of the esophagus, colorectal cancer, internal hemorrhoids, ntestinal 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 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 Hb. 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 reccommended 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.

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ZOAN™

Feces Occult Blood / Transferrin Combo Test Kit Instructions for Use

Version：A/0

[PRODUCT NAME]

Feces Occult Blood / Transferrin Combo Test Kit

[PACKAGE SPECIFICATION]

1 Kit/2Kits/5Kits/7Kits/20Kits/25Kits

[INTENDED USE]

The ZOAN™ one-step Feces Occult Blood/Transferrin Combo Test Kit is a rapid and convenient immunochromatographic assay for the qualitative detection of human hemoglobin and transferrin in human feces specimens. It is used as an aid in the diagnosis of gastrointestinal bleeding caused by gastrointestinal diseases such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn' s disease. This assay provides only a preliminary result. It is recommended to seek for medical advice in conjunction with the test result. This test kit is suitable for use in laboratories and physician's offices as well as for over counter use.

For in vitro diagnostic use only.

For prescription use and over the counter use.

[PRINCIPLE]

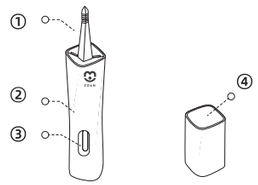
The Fecal Occult Blood / Transferrin Combo Test Kit is a rapid qualitative assay based on the principle of antigen-capture immunochromatographic, detecting the presence of transferrin and fecal occult blood in one single fecal sample. Mouse monoclonal antibodies specifically against human transferrin and hemoglobin, respectively, are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test zone (T1, T2) on the nitrocellulose membrane.

When a fecal extraction sample is added, it rehydrates the gold-antibody conjugate and the transferrin and/or hemoglobin, if any in samples, interact with the colloidal gold conjugated antibodies(transferrin/hemoglobin antibodies 2 on the conjugate pad) and form the antigen-antibody colloidal gold complexes. The antigen-antibody-colloidal gold complexes will migrate towards the test window until the test zone (T1and T2 line) where they are captured by antibodies(transferrin/hemoglobin antibodies 1 on the nitrocellulose membrane), forming a visible red line (indicate positive results). If transferrin and hemoglobin is absent in the sample, no red line will appear in the test zone (T1 and T2 line),indicate negative results.

[COMPONENTS]

Each test device consists of below:

① Built-in sample collection part
② Test device handle
③ Result display window (T1/T2/C)
④ Extraction buffer cap



[MATERIALS PROVIDED]

Components	1 Kit	2 Kits	5 Kits	7 Kits	20 Kits	25 Kits
Test Device	1	2	5	7	20	25
Extraction Buffer Cap	1	2	5	7	20	25
Clean Collection Paper	1	2	5	7	20	25
Instructions for Use	1	1	1	1	1	1

[MATERIALS REQUIRED BUT NOT PROVIDED]

• Clock, timer or stopwatch

[STORAGE AND STABILITY]

Store test kit at: 2℃-30℃ until the expiration date indicated on the label.

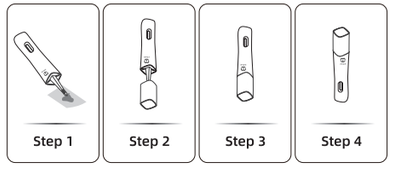
Avoid exposure to direct sunlight. The test kit is stable for 24 months when unopened.

The test should be performed within 1 hour when opened.

[QUICK TEST GUIDE]

Please see below figure.

For detailed operation procedures, please read User Instruction Guide on Page 1.



- **Step 1**: Collect specimen
- **Step 2**: Insert the test device into the buffer cap
- **Step 3**: Waiting for reaction
- **Step 4**: Read the results

[SPECIMEN TYPE]

The specimen type of ZOAN™ FOB/TRF combo test kit is human feces.

-Take samples in observance of the standard precautions for the withdrawal of biological fluids.

[CUT-OFF]

The ZOAN™ test kit could detect Hb in samples at level 50ng/mL, and TRF at level 38ng/mL. The negative percent agreement (NPA) is 95% while performing tests on 240 healthy patients.

[WARNINGS AND PRECAUTIONS]

1.For in vitro diagnostic use only.

2.Do not use after expiration date.

3.Do not eat, drink or smoke in the area where the specimens or kits are handled.

4.Handle all specimens as if they contain infectious agents.

5.Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.

6.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

7.Humidity and temperature can adversely affect results.

8.Please read the Instructions for Use seriously before using the kit.

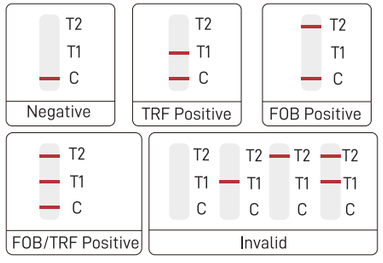
9.Do not use the kit with an obviously damaged package.

10.Do not reuse any kit components.

11.Do not use with multiple specimens.

[INTERPRETATION OF RESULTS]

- **TRF positive:** Two distinct colored lines appear. One line should be in the control region (C) and the other line should be in the test region 1(T1).
- **FOB positive:** Two distinct colored lines appear. One line should be in the control region(C) and the other line should be in the test region 2 (T2) .
- **Negative:** One colored line appears in the control region (C). No apparent red or pink appears in the test regions (T1 and T2) .
- **FOB/TRF positive:** Three distinct colored lines appear. Three lines should be respectively in the control region (C) and test regions (T1/T2).
- **Invalid:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most possible reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
- **Caution:** The user should not take any decision of mdedical relevance without first consulting his or her medical practitioner.



[LIMITATIONS]

1.This test kit is to be used for the qualitative detection of human hemoglobin and transferrin in fecal samples. A positive result suggests the presence of human hemoglobin and transferrin in fecal samples. The presence of blood in stools may be due to several causes, besides colorectal bleeding, such as hemorrhoid, blood in urine or stomach irritations.

2.The ZOAN™ FOB/TRF Test Kit is for in vitro diagnostic use only.

3.Not all colorectal bleedings may not be due to precancerous or cancerous polyps. The data obtained by this test should be used in conjunction with other clinical findings and testing methods, such as barium enema, sigmoidoscopy or colonoscopy.

4.The ZOAN™ FOB/TRF will only indicate the presence of human hemoglobin and transferrin in the specimen. The presence of blood in feces can also have other reasons than colorectal bleeding.

5.Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.

6.Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.

7.This test may be less sensitive for detecting upper g.i. bleeding because blood degrades as it passes through the g.i. track.

8.As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

9.Other clinically available tests are required if questionable results are obtained.

[QUALITY CONTROL]

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements.

[PERFORMANCE]

Sensitivity

The ZOAN™ Fecal Occult Blood/Transferrins Combo Test Kit can detect level of FOB as low as 50ng/mL and detect level of TRF as low as 38ng/mL.

Positive Percent Agreement (PPA)

FOB: While detecting FOB positive reference material, the results should be all positive.

TRF: While detecting TRF positive reference material, the results should be all positive.

Negative Percent Agreement (NPA)

FOB: While detecting FOB negative reference material, the results should be all negative.

TRF: While detecting TRF negative reference material, the results should be all negative.

Repeatability

FOB: The repeatability of FOB should be 100%

TRF: The repeatability of TRF should be 100%

Precision

FOB: The color between test regions and control region should be same.

TRF: The color between test regions and control region should be same.

Prozone Effect

There will be hook effect if detecting the human hemoglobin positive reference material with concentration higher than 2000μg/mL and detecting human transferrin positive reference material with concentration higher than 400μg/mL.

Interference

Below interferents were used in interference study for ZOAN™ FOB/TRF test kit. Specimen containing the following substances at the standard concentration were tested on both positive and negative controls with no effect on test results.

Interferent	Concentration	Interferent	Concentration
Pork meat extract	0.5mg/mL	Rabbit meat extract	0.5mg/mL
Beef meat extract	0.5mg/mL	Horseradish peroxidase	2mg/mL
Goat meat extract	0.5mg/mL	Myoglobin	500μg/mL
Dog meat extract	0.5mg/mL	Vitamin C	2000μg/mL
Chicken meat extract	0.5mg/mL	Distilled water	/

Accuracy

The ZOAN™ Fecal Occult Blood/Transferrins Combo Test Kit has been compared with another leading commericial rapid test using clinical specimens.

Method		Other Rapid Test		
		Positive	Negative	Total
ZOAN™ Test Kit	Positive	145	2	147
	Negative	5	348	353
	Total	150	350	500

Relative sensitivity:145/150=96.7%
Relative sensitivity:348/350=99.4%
Accuracy:(145+338)/(145+5+2+348)=98.6%

Others

Strip width: ≥2.5mm

Liquid flow speed: ≥10mm/min

[SYMBOLS USED ON LABELS]

	Use-By date		Consult Instructions for use
LOT	Batch code		Do not freeze
	Manufacturer		Biological risks
	Keep Away from Sunlight	Σ	Contains sufficient for <n> tests
	Temperature Limit		Do not use if package is damaged
IVD	In Vitro Diagnostic Medical device		Date of manufacture
CE	CE Mark		Do Not Reuse
EC REP	Authorized Representative in the European Community		

Manufacturer
Shijiazhuang Hipro Biotechnology Co., Ltd.
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[Approval date and date of revision]

Approval Date: Aug 30, 2022

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