CE IVD

Human Transferrin Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Transferrin Antigen in human fecal specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Human Transferrin Antigen Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The Human Transferrin Antigen Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human Transferrin in human Fecal Specimen.

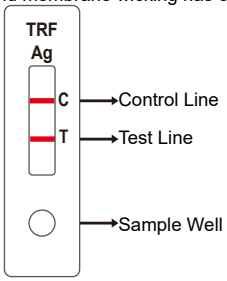
INTRODUCTION

Many diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restrictions prior to testing. Tf is a type of β1 globulin, with a molecular weight of 77 KD, accounts for about 0.3% to 0.5% of the total plasma protein. It is mainly synthesized in liver, and the main function of the protein is to transport extracellular iron into cells through membrane receptor-mediated endocytosis. 3 As in the case of transferrin, serum Tf may be leaked into gastrointestinal tract during the course of bleeding. However, compared with transferrin, Tf is more stable.

Human Transferrin Antigen Rapid Test Kit (Colloidal Gold)is a rapid test to qualitatively detect low levels of Transferrin of fecal occult blood in feces. The test uses double antibody sandwich assay to selectively detect as low as 40ng/mL transferrin of human occult blood in feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Human Transferrin Antigen Rapid Test Kit (Colloidal Gold) is a qualitative, lateral flow immunoassay for the detection of human occult blood in feces. The membrane is pre-coated with anti-transferrin antibody on the test line region of the strip. During testing, the specimen reacts with the particle coated with anti-transferrin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-transferrin antibody on the membrane and generate a colored line. The presence of this colored line in the test 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 the proper volume of specimen has been added and membrane wicking has occurred.



COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution	1mL/bottle, 25pcs	1mL/bottle, 5pcs	1mL/bottle, 1pcs
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:

Mouse anti-Human Transferrin antibody, Goat anti-rabbit IgG polyclonal antibody, Human Transferrin antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant.

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C

STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below.

Procedure A: Solid stool samples

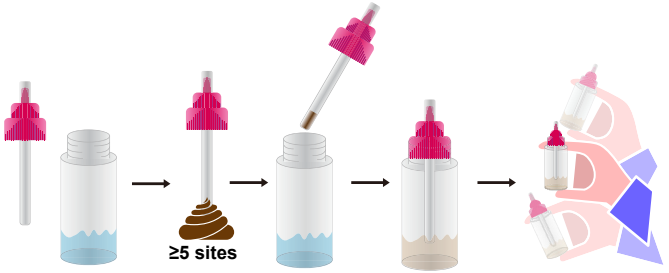
Step 1: Collect a random stool sample in a clean, dry receptacle.

Step 2: Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.

Step 3: Ensure stool sample is only in the grooves of the collection stick. **Excess stool sample may lead to an invalid test result.**

Step 4: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously.



Procedure B: Watery stool samples

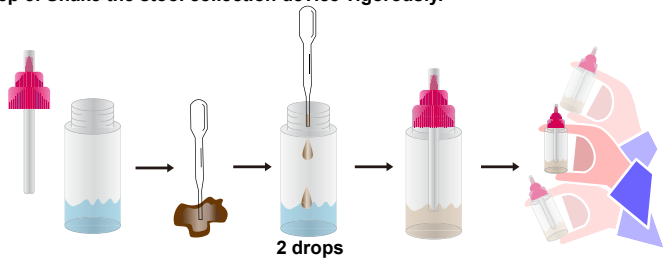
Step 1: Collect a random stool sample in a clean, dry receptacle.

Step 2: Open the stool collection device by unscrewing the top.

Step 3: Fill the plastic dropper with the sample; dispense 2 drops (70-85uL) into the stool collection device.

Step 4: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously.



Note: Specimens extracted may be stored at 2-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.

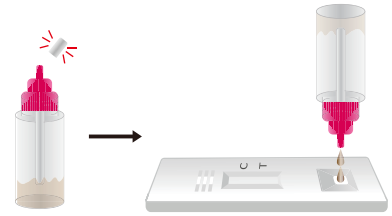
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen.

Step 2: When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure an effective liquid suspension.

Step 4: Position the stool collection device upright and twist off the dispenser cap. Holding the stool collection device vertically, dispense 2 drops of the solution (85-95uL) into the sample well of the test device. Do not overload sample.



Step 5: Set up timer.

Step 6: Results can be read after 15 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

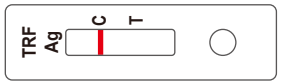
Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the

test procedure and to verify proper test performance.

INTERPRETATION OF ASSAY RESULT

Negative Control

One colored band appears in the control band region (C). No band appears in the test band region (T).

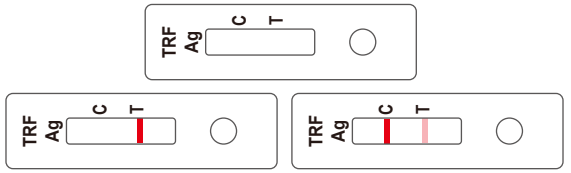


Positive Control:

A colored band appears in the control band region (C) and another colored band appears in the T band region.

INVALID:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must bediscarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



*NOTE: The intensity of color in the test line region (T) will vary depending on the concentration of transferrin present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

PERFORMANCE CHARACTERISTICS

Accuracy

The Transferrin Rapid Test Kit has been compared with another leading commercial rapid test using clinical specimens:

Method		Other Rapid Test		
TF Rapid Test Device	Results	Positive	Negative	
	Positive	203	5	208
	Negative	10	603	613
Total Results		213	608	921
Relative Sensitivity: 95.3 %(91.5% -97.7%)* Relative Specificity: 99.2% (98.1% - 99.7%)* Relative Accuracy: 98.2 %(97.0%-99.0%)*			* 95% Confidence Intervals	

Sensitivity

The Transferrin Rapid Test Kit can detect the levels of human occult blood as low as 40 ng/mL transferrin.

Specificity

The Transferrin Rapid Test Kit is specific to human transferrin. Specimen containing the following substances at the standard concentrations were tested on both positive and negative controls with no effect on test results.

Substances	Concentrations (Diluted with the extraction buffer)
Bovine transferrin	0.4 mg/mL
Chicken transferrin	0.4mg/mL
Pork transferrin	0.4 mg/mL
Goat transferrin	0.4 mg/mL
Horse transferrin	0.4 mg/mL
Rabbit transferrin	0.4 mg/mL

EXPECTED VALUES

The Human Ferritin Rapid Test Kit has been compared with another leading commercial rapid test. The correlation between these two systems is 99.8%.

TEST LIMITATIONS

1.The Transferrin Rapid Test Kit is for in vitro diagnostic use only.
2.The Transferrin Rapid Test Kit will only indicate the presence of human transferrin in the specimen, 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.
4.Other clinically available tests are required if questionable results are obtained.

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
3.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
4.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
5.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
6.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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