BoatBIO

Human Ferritin Antigen Rapid Test Kit (Colloidal Gold)

CE

IVD

Instruction for Use

Read this instruction carefully before use.

A rapid test for the qualitative detection of Human Ferritin Antigen in human whole blood, serum and plasma. For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Human Ferritin Antigen Rapid Test Kit (Colloidal Gold)

SPCIFICATION

40 tests/kit;25 tests/kit; 5 tests/kit

INTENDED USE

The Human Ferritin Antigen Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human Ferritin in human whole blood, serum and plasma.

INTRODUCTION

Ferritin is a universal intracellular protein that stores iron and releases it in a controlled fashion. The protein is produced by almost all living organisms, including algae, bacteria, higher plants, and animals. In humans, it acts as a buffer against iron deficiency and iron overload. Ferritin is found in most tissues as a cytosolic protein, but small amounts are secreted into the serum where it functions as an iron carrier. Plasma ferritin is also an indirect marker of the total amount of iron stored in the body, hence serum ferritin is used as a diagnostic test for iron deficiency anemia. Ferritin is a globular protein complex consisting of 24 protein subunits and is the primary intracellular iron-storage protein in both prokaryotes and eukaryotes, keeping iron in a soluble and non-toxic form. Ferritin that is not combined with iron is called apoferritin.
Human Ferritin Antigen Rapid Test Kit (Colloidal Gold) is a rapid test to qualitatively detect human Ferritin in human whole blood, serum and plasma. The test uses double antibody sandwich assay to selectively detect as low as 20ng/mL human Ferritin in human whole blood, serum and plasma.

PRINCIPLE

Human Ferritin Antigen Rapid Test Kit (Colloidal Gold) is a qualitative, lateral flow immunoassay for the detection of human Ferritin in human whole blood, serum and plasma. The membrane is pre-coated with anti-ferritin antibody on the test line region of the strip. During testing, the specimen reacts with the particle coated with anti-ferritin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-ferritin 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	40tests/kit	25tests/kit	5test/kit
Cassettes	40 cassettes with dependent sealed foil pouch	25 cassettes with dependent sealed foil pouch	5 cassette with dependent sealed foil pouch
Sample Diluent Solution	7 ml/bottle	5 ml/bottle	1 ml/bottle
Dropper	40pcs	25 pcs	5 pcs
Package insert	1	1	1

Main ingredients of test cassettes:

Mouse anti-Human Ferritin antibody, Goat anti-rabbit IgG polyclonal antibody, Human Ferritin 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

PERCAUTIONS

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 bio-safety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2.Separate the plasma by centrifugation.
3.Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

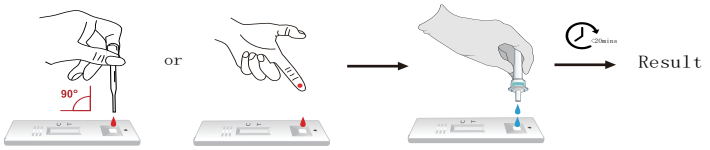
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.
Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

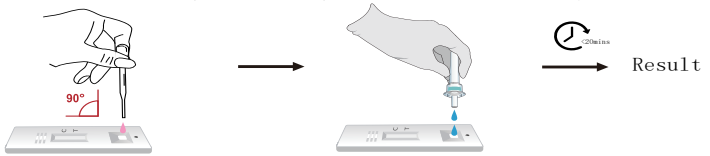
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.

Step 4: For whole blood test
- Apply 1 drop of whole blood (about 20 μL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test
- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5:Set up timer.
Step 6: Results can be read in 20 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.

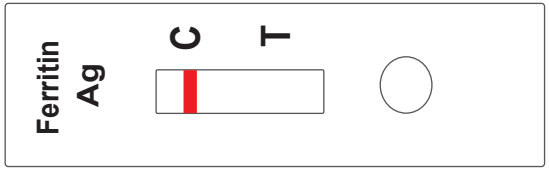
QUALITY CONTROL

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

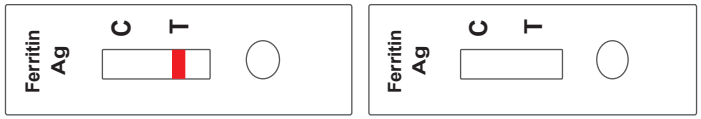
One colored band appears in the control band region (C). No band appears in the test band region (T).



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 Device (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total Results
TF Rapid Test Device	Results	Positive	Negative	20
	Positive	20	0	20
	Negative	0	20	

Relative Sensitivity: >99.9 % Relative Specificity: >99.9 % Relative Accuracy: >99.9 %

Sensitivity
The Human Ferritin Rapid Test Kit (Colloidal Gold) can detect the levels of human ferritin as low as 20 ng/mL ferritin.

Interfering Substances
The Human Ferritin Rapid Test Kit (Colloidal Gold) has been tested and no interference was observed in specimens containing 110mg/mL human albumin, 6 mg/mL bilirubin, 5 mg/mL cholesterol and 15 mg/mL triglycerides.
The following compounds have also been tested using Human Ferritin Rapid Test Kit (Colloidal Gold) and no interference was observed at a concentration of 50μg/mL.

Name	Name	Name	Name
Acetaminophen	Atenolol	Fumarate	Chlordiazepoxide
Acetylsalicylic Acid	Atorvastatin	Caffeine	Cilazapril
Anisodamine	Calcium	Captopril	Diclofenac
Ascorbic Acid	Bisoprolol	Chloramphanicol	Digoxin

Name	Name	Name	Name	Name	Name
Erythr-omycin	Hydroch-loride	Labetalol	Nifedipine	Quinine	Verap-amil
Felodipine	Hydrochl-orothiazide	Metoprolol Tartrate	Oxazepam	Ramipril	
Furosemide	Isosorbide	Moracizine	Pentoxifyline	DL-Tyrosine	
Flunarizine	Mononitrate	Hydro-chloride	Phenobarbital	Trimethoprim	

EXPECTED VALUES

The Human Ferritin Rapid Test Device (Colloidal Gold) has been compared with another leading commercial rapid test. The correlation between these two systems is 99.8%.

TEST LIMITATIONS

1.The Human Ferritin Rapid Test Kit (Colloidal Gold) is for in vitro diagnostic use only. This test should be used for the detection of human ferritin in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in human ferritin can be determined by this qualitative test.
2.The Human Ferritin Rapid Test Kit (Colloidal Gold) will only indicate the qualitative level of human ferritin in the specimen.
3.The Human Ferritin Rapid Test Kit (Colloidal Gold) cannot detect less than 20 ng/mL of human ferritin in specimens. A negative result at any time does not preclude the possibility of anemia of chronic disease.
4.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5.Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

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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