Ferritin Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

REF OFE-402	English

A rapid test for the qualitative detection of ferritin in human serum, plasma and whole blood for iron deficiency anemia.

For professional in vitro diagnostic use only

【INTENDED USE】

The Ferritin Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of human ferritin in human serum or plasma and whole blood at a cut-off concentration of 30ng/ml.

【SUMMARY】

Ferritin is a universal intracellular protein that stores iron and releases it in a controlled fashion. Plasma ferritin is 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. [1]

A normal ferritin blood level, referred to as the reference interval is determined by many testing laboratories. In most tissues, ferritin is a major iron storage protein. Human ferritin has a molecular weight of approximately 450,000 Daltons, and consists of a protein shell around an iron core; each molecule of ferritin may contain as many as 4,000 iron atoms. Under normal conditions, this may represent 25% of the total iron found in the body. In addition, ferritin can be found in several isomers.

If the ferritin level is low, there is a risk for lack of iron, which could lead to anemia. Low ferritin may also indicate hypothyroidism, vitamin C deficiency or celiac disease. Low serum ferritin levels are seen in some patients with restless legs syndrome, not necessarily related to anemia, but perhaps due to low iron stores short of anemia. [2][3]

【PRINCIPLE】

The Ferritin Rapid Test Cassette is aqualitative, lateral flow immunoassay for the detection of human ferritin in human serum or plasma and whole blood. The membrane is precoated with anti-ferritin polyclonal antibody on the test line region. And the membrane is precoated with Goat anti Rabbit IgG on the reference line region. The gold is precoated with anti-ferritin monoclonal antibody and Rabbit IgG. During testing, the specimen reacts with the particle coated with anti-ferritin monoclonal antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-ferritin polyclonal antibody on the membrane and generate a colored line. The line in test line region (T) appears, if the ferritin level exceeds the cut-off level of 30ng/ml. If the ferritin concentration is less than 30ng/ml, the test line not appears. 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.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- **For Serum or Plasma Specimen**
- Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.
- Serum or Plasma specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing. Specimens should not be frozen and thawed repeatedly.
- **For Whole Blood specimens**
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test Cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

  If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agent.

【MATERIALS】

Materials provided

- Test Cassettes
- Droppers
- Buffer
- Package Insert

Materials required but not provided

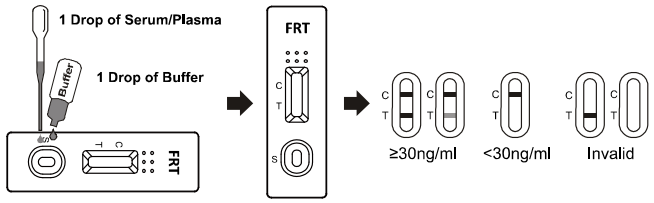
- Specimen collection containers
- Timer
- Lancets (for fingerstick whole blood only)
- Centrifuge
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing

For serum or plasma specimen:

1. Bring the pouch to room temperature (15-30 °C) before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 1 full drop of serum or plasma (approximately 25ul) to the specimen well of the cassette, then add **1 drop of buffer** (approximately 40µl) and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line(s) to appear. Read the result at 5 minutes when testing a serum or plasma specimen.



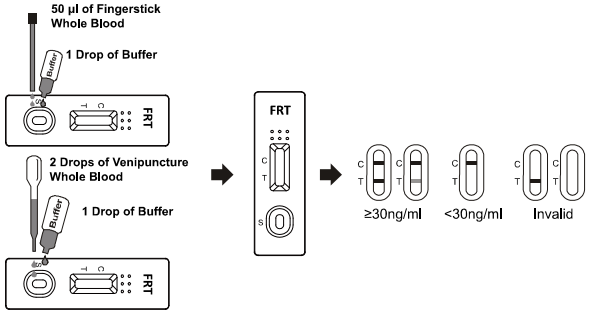
For whole blood specimen:

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.

   Place the cassette on a clean and level surface.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 50µl) to the specimen well, then **add 1 drop of buffer** (approximately 40µl), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 50µl of fingerstick whole blood specimen** to the specimen area of test cassette, then add **1 drop of buffer** (approximately 40µl) and start the timer. See illustration below.
2. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration)

≥30ng/ml: Two lines appear. The line in test line region (T) appears. It depicts no iron deficiency anemia, unless Ferritin levels are raised due to some other reasons.

<30ng/ml: One line appears. Only control line appears (C) . There may be a risk of anemia.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【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.

【LIMITATIONS】

1. The Ferritin Rapid Test Cassette provides only a qualitative analytical result. A secondary analytical method must be used to obtain a confirmed result.
2. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood specimen may cause erroneous results.
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.

【EXPECTED VALUES】

This result of <30ng/ml indicates that the ferritin concentration is too low, there may be a risk of anemia.

【PERFORMANCE CHARACTERISTICS】

Accuracy

The Ferritin Rapid Test Cassette has been compared with CLIA.

The following results were tabulated:

Precision

Method		CLIA		Total Result
	Results	Abnormal	Normal	
Ferritin Rapid Test Cassette	Abnormal	21	3	24
	Normal	2	76	78
Total Result		23	79	102

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 30ng/ml, 100ng/ml and 300ng/ml specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same 3 specimens: 30ng/ml ferritin, 100ng/ml ferritin, 300ng/ml ferritin standard sample. Three different lots of the Ferritin Rapid Test Cassette have been tested using these specimens. The specimens were correctly identified >99% of the time.

Analytical Sensitivity

The Ferritin Rapid Test Cassette can detect levels of ferritin in human serum, plasma and whole blood as low as 30ng/ml.

Cross-Reactivity

An evaluation was performed to determine the cross reactivity and interferences of Ferritin Rapid Test Cassette. There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in human serum, plasma and whole blood.

【BIBLIOGRAPHY】

1. Wang W, Knovich MA, Coffman LG, Torti FM, Torti SV (August 2010)."Serum ferritin: Past, present and future". Biochim. Biophys. Acta 1800(8): 760–9.
2. Kryger MH, Otake K, Foerster J (March 2002). "Low body stores of iron and restless legs syndrome: a correctable cause of insomnia in adolescents and teenagers".Sleep Med. 3 (2): 127–32.
3. Mizuno S, Mihara T, Miyaoka T, Inagaki T, Horiguchi J (14 March 2005). "CSF iron, ferritin and transferrin levels in restless legs syndrome". J Sleep Res 1: 43–7.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou AllTest Biotech Co., Ltd.
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