Ferritin Rapid Test Cassette
(Whole Blood)
Package Insert
For Self-testing

The Ferritin Rapid Test Cassette is a rapid test for the qualitative detection of ferritin in human fingerstick blood for iron deficiency anemia.
For self-testing in vitro diagnostic use only.

【INTENDED USE】

The Ferritin Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of ferritin in human fingerstick blood at a cut-off concentration of 30 ng/mL.

【SUMMARY】

Anemia due to iron depletion is widely held in children and women of all ages but mainly in women who still have their periods (at least 20% suffer from iron deficiency). Main signs are paleness, feeling tired, headaches, faster heartbeat, or shortness of breath during exercise. They may appear gradually and could go unnoticed.

Iron deficiency occurs when blood does not contain enough red blood cells and thus low levels of hemoglobin, which is the major protein involved in oxygen transport in whole body. An important component of hemoglobin is iron.

Depletion of iron, which can happen during pregnancy, growth, in case of insufficient iron intake, inadequate absorption or blood loss (period, abnormal bleedings, ulcers, etc.) has tremendous effects on health.

Low ferritin may also indicate hypothyroidism, vitamin C deficiency or celiac disease. Low 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.[1,2]

【PRINCIPLE】

The Ferritin Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of human ferritin in human whole blood. The membrane is precoated with anti-ferritin polyclonal antibody on the test line region. The gold is pre-coated 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 30 ng/mL. If the ferritin concentration is less than 30 ng/mL, the test line does not appear. 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 self-testing *in vitro* diagnostic use only.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- The used test should be discarded according to local regulations.

【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. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS PROVIDED】

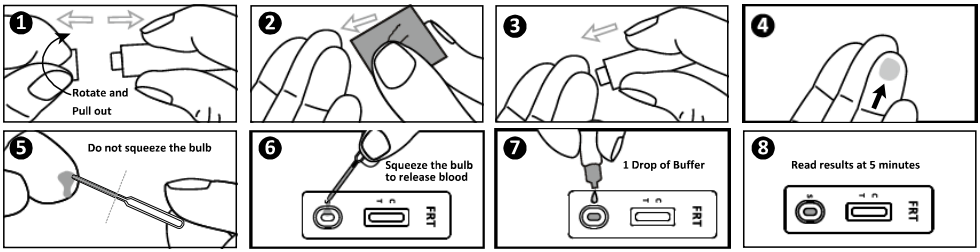
• Test cassette • Capillary dropper • Buffer • Alcohol pad • Lancet • Package insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

• Timer

【PROCEDURE】

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it. Open the foil pouch and get out the cassette.
3. Carefully pull off and dispose the released cap of the lancet.
4. Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site.
5. Press the lancet, on the side from where the cap was extracted; against the fingertip (it is advisable the ring finger side).The tip retracts automatically and safely after use.
6. Keeping the hand down massage the end that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood migrates into the capillary dropper through the capillarity to the line indicated on the capillary dropper.
   You may massage again your finger to obtain more blood if the line is not reached. As far as possible, avoid of air bubbles.
8. Put the blood collected into the sample well of the cassette, by squeezing the dropper bulb.
9. Wait for the blood to be totally dispensed in the well. Unscrew the cap of the buffer bottle and add **1 drop of buffer** into the sample well of the cassette.
10. Wait for the colored line(s) to appear. Read results at **5 minute**s. Do not interpret the result after 10 minutes.



【READING THE RESULTS】

Normal: Two colored lines appear. Both T (Test) and C (Control) line appear. This result means that the Ferritin concentration in blood is normal and that there is no potential iron deficiency.

Abnormal: One colored line appears. **Only control line（C）appears.**
This result means that the ferritin concentration in blood is too low. You should consult physician because it may be an iron deficiency.

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.

【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.

【PERFORMANCE CHARACTERISTICS】

The specimen correlation used a specimen number (n) equal to 102 specimens, including 79 normal whole blood specimens and 23 abnormal whole blood specimens were confirmed by CLIA. The result demonstrated showed that the abnormal coincidence rate is 91.3%, the normal coincidence rate is 96.2% and the total coincidence rate is 95.1%.

Ferritin Rapid Test Cassette Result

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

Abnormal coincidence rate=21/(21+2)*100%=91.3%
Normal coincidence rate=76/(3+76)*100%=96.2%
Total coincidence rate=(21+76)/ (21+3+2+76) *100% = 95.1%

Accuracy

The Ferritin Rapid Test Cassette has been compared with a leading commercial Ferritin CLIA test. The correlation between these two systems is over 95.0%.

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens: 0 ng/mL, 30 ng/mL and 100 ng/mL specimens. The specimens were correctly identified > 99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same 3 specimens: 0 ng/mL ferritin, 30 ng/mL ferritin, 100 ng/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 fingerstick blood as low as 30 ng/mL.

Cross-Reactivity

An evaluation was performed to determine the cross reactivity and interferences of Ferritin Rapid Test Cassette. There is no cross reactivity with HAMA, RF, Human serum albumin, human AFP, Ferric Chloride, human transferrin and human hemoglobin.

【EXTRA INFORMATIONS】

1. How does the ferritin test work?

Ferritin is a protein and the primary form of iron stored inside cells. An abnormal result means that the ferritin concentration in blood is lower than 30 ng/mL and a possible iron deficiency.

2. When should the test be used?

The Ferritin Rapid Test Cassette can be performed in case of symptoms like paleness, feeling tired, headaches, faster heartbeat or shortness of breath during exercise; mainly, if woman, when pregnant or in case of excessive bleeding during periods. The test can be performed anytime of the day, but must not be performed in case of disease, acute inflammations or in case of spleen or liver injury. Abnormal results can be obtained even in case of no iron deficiency situation.

3. Can the result be incorrect?

The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if the ferritin test gets wet before test performing or if the quantity of blood dispensed in the sample well is not sufficient. The capillary dropper provided in the box allows making sure the collected blood volume is correct. Besides, due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. What is the line that appears under the C (control) line?

When this line appears, it only means that the test is performing well.

5. If i read the result after 10 minutes, will the result be reliable?

No. The result should be read at 5 minutes after adding the buffer. The result is not reliable after 10 minutes.

6. What do i have to do if the result is abnormal?

If the result is abnormal, it means that the ferritin level is lower than the normal (30 ng/mL) and that you should consult the physician and show the test result to him/ her. Then, the physician will decide whether additional analysis should be performed.

7. What do i have to do if the result is normal?

If the result is normal, it means that the ferritin level is higher than 30 ng/mL and is within the normal range. However, if the symptoms persist, it is recommended to consult a physician.

【BIBLIOGRAPHY】

1. 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".SleepMed.3 (2): 127–32.
2. 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 Res1: 43–7.

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