

**【INTENDED USE】**

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.

**【SUMMARY】**

Ferritin is a blood protein that stores Iron, and is therefore a good indicator of how much Iron is stored in the body. Anemia due to iron depletion is widely found in children and women of all ages but predominately in women who still have their periods (at least 20% suffer from iron deficiency). Symptoms include paleness, feeling tired, headaches, faster heartbeat, or shortness of breath during exercise. Symptoms 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 the 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.<sup>1,2</sup>

**【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 a 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.
- Blood samples should not be taken from fingers on the side affected by a mastectomy.

**【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 until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**【MATERIALS PROVIDED】**

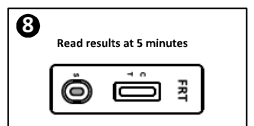
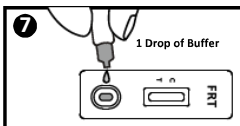
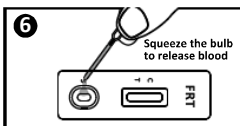
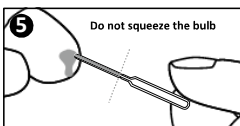
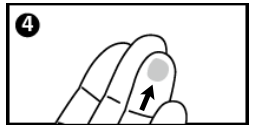
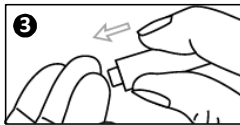
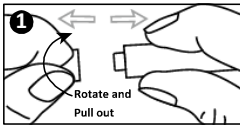
- Test cassette • Capillary dropper • Buffer • Alcohol pad • Lancet • Package insert

**【MATERIALS REQUIRED BUT NOT PROVIDED】**

- Timer

**【PROCEDURE】**

1. Wash your hands with soap and rinse with warm water.
2. Bring the pouch to room temperature prior to opening. Open the foil pouch and remove the cassette.
3. Carefully remove the cap of the lancet and dispose. Do not remove the lancet cap until you are ready to perform the test and complete in full.
4. Use the provided alcohol pad to clean the identified puncture site on the middle or ring finger allow to air-dry.
5. Place the lancet, on the side from where the cap was removed against the fingertip. Apply gentle and steady pressure for 2-3 seconds until a click is heard. The lancet tip will retract automatically and safely after use.
6. Keeping the hand down, gently massage the finger that was punctured to obtain a drop of blood.
7. Without squeezing the capillary dropper bulb, place it in contact with the formed drop of blood. The blood will automatically be drawn up the capillary dropper to the fill line. You may continue to massage your finger to obtain more blood if the line is not reached. Try to avoid the creation of air bubbles.
8. Immediately add the blood sample to the well of the cassette by squeezing the dropper bulb carefully.
9. Wait for the blood to totally dispense 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 coloured line(s) to appear. Read results at **5 minutes**. Do not interpret the result after 10 minutes.


**【READING THE RESULTS】**


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



**Abnormal: One line appears. Only control line appears (C).**

This result means that the ferritin concentration in the blood is too low. You should consult your physician because it may be due to 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 only provides a qualitative analytical result. A secondary analytical method must be used to confirm 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 alongside other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

**【EXTRA INFORMATIONS】**

**1. HOW DOES THE FERRITIN TEST WORK?**

Ferritin is a protein that stores Iron within the bodies cells. An abnormal result means that the ferritin concentration in the blood is lower than 30 ng/mL and iron deficiency is a possibility.

**2. WHEN SHOULD THE TEST BE USED?**

The Ferritin Rapid Test Cassette can be performed if the following symptoms are experienced; paleness, feeling tired, headaches, faster heartbeat or shortness of breath during exercise; mainly, in 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 if Iron is not deficient.

**3. CAN THE RESULT BE INCORRECT?**

The results are accurate as long as the instructions are carefully followed. Nevertheless, the result can be incorrect if the ferritin test becomes wet prior to the test being performed or if the quantity of blood dispensed in the sample well is not sufficient. The capillary dropper provided in the kit ensures the collected blood volume is correct. As with all immunological assays, there is the possibility of obtaining a false result. 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 means the test procedure has been followed correctly.

**5. IF I READ THE RESULT AFTER 10 MINUTES, WILL THE RESULT BE RELIABLE?**

No. The result should be read at 5 minutes following the addition of 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 your doctor and discuss the test result. The doctor will decide whether additional testing 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 symptoms persist, it is recommended to consult your doctor.

**【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 Res: 43–7.

**Index of Symbols**

|  |   |
|--|---|
|  | Manufacturer                            |
|  | For <i>in vitro</i> diagnostic use only |
|  | Store between 2-30°C                    |
|  | Do not use if package is damaged        |

|  |                              |
|--|------------------------------|
|  | Tests per kit                |
|  | Use by                       |
|  | Lot Number                   |
|  | Consult Instructions For Use |

|  |                           |
|--|---------------------------|
|  | Authorized Representative |
|  | Do not reuse              |
|  | Catalog #                 |
|  |                           |

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