

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

【SUMMARY】

Anaemia 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 haemoglobin, which is the major protein involved in oxygen transport throughout the body. An important component of haemoglobin 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 serious effects on health.

Low ferritin may also indicate hypothyroidism, vitamin C deficiency or coeliac disease. Low ferritin levels are seen in some patients with restless legs syndrome, not necessarily related to anaemia, but perhaps due to low iron stores short of anaemia.^{1,2}

【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.

【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】

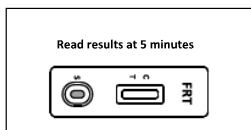
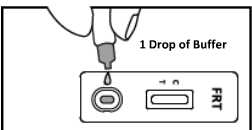
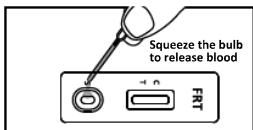
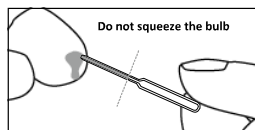
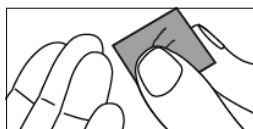
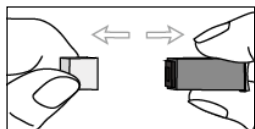
- Test cassette
- Capillary Dropper
- Buffer
- Alcohol pad
- Lancets
- Package insert

【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 of the clear plastic cap of the lancet. The lancet is a single use lancet so make sure you do not fire the lancet prematurely.
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 removed) firmly against the fingertip (the side of the ring or middle finger is advised). The tip retracts automatically and safely after use.
6. Keeping the hand down, massage the finger that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, gently put it in contact with the edge of the blood drop. The blood should automatically be drawn up the dropper by capillary action. You should fill the dropper up to the black line. You may continue to massage your finger to obtain more blood if the line is not reached. As far as possible, try to avoid air bubbles.
8. Transfer the collected blood into the sample well (S) 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 coloured line(s) to appear. Read results at **5 minutes**. Results obtained after this time may be inaccurate.



【READING THE RESULTS】



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



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

This result means that the ferritin concentration in blood is too low. You should consult a physician because you may have 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.

【FAQs】

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 30ng/ml which indicates 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, or in women whom are pregnant or experiencing excessive bleeding during periods. The test can be performed any time of the day, but must not be performed in case of disease, acute inflammations or in case of spleen or liver injury as you may get abnormal results even if there is no iron deficiency.

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 testing or if the quantity of blood dispensed in the sample well is not sufficient. The capillary dropper provided in the box allows you to make sure the collected blood volume is correct. In addition, due to immunological principles involved, there is the possibility of false results in rare cases. A consultation with a 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 has worked.

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 normal (30ng/ml) and that you should consult your 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 30ng/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 Res: 43-7.

Index of Symbols

	Attention, see instructions for use
	For in vitro 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 #
	Manufacturer

 **Hangzhou AllTest Biotech Co., Ltd.**
 #550, Yinhai Street
 Hangzhou Economic & Technological Development Area
 Hangzhou - 310018, P. R. China
 www.alltests.com.cn

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