

Iron Deficiency Test

Self-test • ferritin rapid test • cassette • whole blood

ENGLISH

The Iron Deficiency Test (ferritin rapid test) is a rapid test for the qualitative detection of ferritin in human fingerstick blood to aid the diagnosis of iron deficiency and anaemia. For self-testing in vitro diagnostic use only. For self-testing in vitro diagnostic use only.

[SUMMARY]

Anaemia due to iron depletion, is common in children and adults of all ages, particularly in menstruating women (at least 20% suffer from iron deficiency). The main symptoms are extreme fatigue, difficulty concentrating, headache, pale skin, muscle and joint pain, weight gain, palpitations, sometimes associated with sleep disturbances, weakness, chest pain, fast heartbeat or shortness of breath. Iron deficiency anaemia occurs when your body doesn't have enough iron to produce haemoglobin. Haemoglobin is the part of red blood cells that gives blood its red colour and enables the red blood cells to carry oxygenated blood throughout your body. If you are not consuming enough iron (lack in diet, inability to absorb iron), or if you're losing too much iron (blood loss, pregnancy), your body can't produce enough haemoglobin, and iron deficiency anaemia will eventually develop.

Mild iron deficiency anaemia usually doesn't cause complications. However, left untreated, iron deficiency anaemia can become severe and lead to health problems, including heart failure, problems during pregnancy, delayed growth and development in children.

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 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.

[MATERIALS PROVIDED]

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

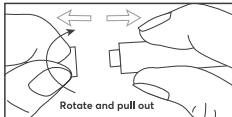
[MATERIALS REQUIRED BUT NOT PROVIDED]

• Timer

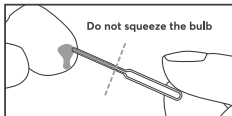
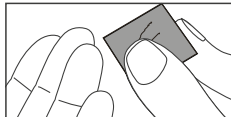
[PROCEDURE]

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 remove the cassette.
3. Carefully pull off and dispose of the 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. The tip retracts automatically and safely after use.
6. Keeping the hand pointing downwards, massage toward the end of the finger that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, place it in contact with the blood. The blood migrates into the capillary dropper to the line indicated on the capillary dropper. You may need to massage your finger again to obtain more blood if the line is not reached. Avoid 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 coloured line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.

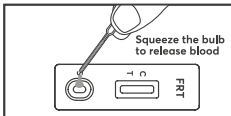
[READING THE RESULTS]



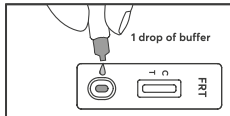
Rotate and pull out



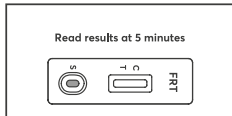
Do not squeeze the bulb



Squeeze the bulb to release blood



1 drop of buffer



Read results at 5 minutes



Normal: Two 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 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 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, discontinuing using the test kit immediately and contact your local distributor.

[LIMITATIONS]

1. The Iron Deficiency (ferritin rapid test) 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.

[EXTRA INFORMATION]**1. HOW DOES THE IRON DEFICIENCY (FERRITIN RAPID 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 and a possible iron deficiency.

2. WHEN SHOULD THE TEST BE USED?

The Iron Deficiency (ferritin rapid test) 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.

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 (30ng/ml) and that you should consult a physician to discuss the test result and 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

	Manufacturer		Tests per kit		Authorised Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		

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