REF OFE-402H

CE 0123

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Instructions for use

ENGLISH

Iron Deficiency (Ferritin) Rapid Test

Ferritin Rapid Test Cassette

INTENDED USE

The Iron Deficiency (Ferritin) Rapid Test is a rapid test for the qualitative detection of ferritin in human finger-prick blood to aid the diagnosis of iron deficiency and anaemia. 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 does not 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 (due to a lack of iron in your diet or, an inability to absorb iron), or if you're losing too much iron (from blood loss, or pregnancy for example), your body cannot 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 and 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]

PRINCIPLE

The Iron Deficiency (Ferritin) Rapid Test 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 Instructions for use 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 in your general household waste

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable up until 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 after the expiration date.

MATERIALS PROVIDED

• Test cassette • Capillary dropper • Buffer • Alcohol pad • Lancet • Plaster • Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

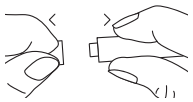
• Timer

PREPARATION

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it.
3. Open the pouch, remove the dropper, buffer vial, lancet, alcohol pad and test cassette placing them on a clean, level surface.
4. Perform the test within one hour with best results obtained if the test is performed immediately after opening the foil pouch.

INSTRUCTIONS

1



Carefully pull off and dispose of the cap on the lancet.

2

Use the alcohol pad to clean the fingertip which will be pricked with the lancet. Allow to air dry.

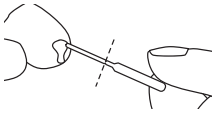
3

Press the orange end of the lancet down against the fingertip to prick the puncture site. The tip retracts automatically and safely after use.

4

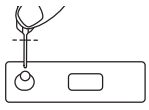
Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.

5



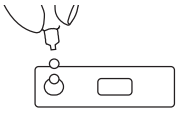
Without squeezing the capillary dropper bulb, place the end of the capillary tube in the blood until it reaches the fill line. Massage your finger again to obtain more blood if the blood does not reach the indicated line. Avoid air bubbles.

6



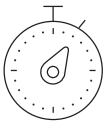
Transfer the collected blood into the sample well (S) of the cassette, by squeezing the dropper bulb. Apply the spot plaster to puncture site if required.

7



Unscrew the cap of the buffer vial and add 2 drops of buffer into the sample well (S) of the cassette.

8



Start a timer and wait for the coloured line(s) to appear.

9

Read results at 5 minutes. Do not interpret the result after 10 minutes.

READING THE RESULTS

Normal		**Normal** **Two coloured 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		**Abnormal** **One coloured 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		**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 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.

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%..

Method		CLIA		Total Results
Iron Deficiency (Ferritin) Rapid Test	**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 Iron Deficiency (Ferritin) Rapid Test has been compared with a leading commercial Ferritin CLIA test. The correlation between these two systems is over 95.0%.

Analytical Sensitivity
The Iron Deficiency (Ferritin) Rapid Test can detect levels of ferritin in human fingerstick blood as low as 30 ng/mL.

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.

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

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 Iron Deficiency (Ferritin) Rapid Test have been tested using these specimens. The specimens were correctly identified >99% of the time.

FAQs

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 30 ng/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 female, 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 cases of disease, acute inflammation, or 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 followed. However, 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 ensures the collected blood volume is correct. Due to immunological principles involved, there is still a chance 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 confirms that the test has performed correctly.

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 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 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.

INDEX OF SYMBOLS

	Manufacturer		Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		


Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China

CE 0123 EC REP MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

Lancet:


Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community,
Yuhang District, Hangzhou City, 311121 Zhejiang, China

CE 0197 EC REP MT Promedt Consulting GmbH, Altenhofstr. 80 66386 St., Ingbert, Germany

OR


Ningbo Medsun Medical Co., Ltd.
No. 55 Jinxi Road, Zhenhai 315221 Ningbo
People's Republic of China

CE 0123 EC REP Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

Alcohol pad:


Jiangsu Sunclean Medical Co., Ltd.
No.11 Fenghuang South Road,
Hutang Town, Wujin District
213162 Changzhou City, Jiangsu Province, P.R. China

CE 0123 EC REP Medpath GmbH, Mies-van-der-Rohe Strasse 8, 80807 Munich, Germany

OR


Ningbo Medsun Medical Co., Ltd.
No. 55 Jinxi Road, Zhenhai 315221 Ningbo
People's Republic of China

CE EC REP Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

Plaster:


Nantong City YOJO Medical Products C, Ltd
Industrial Park, Sanxing Town, Haimen City,
Jiangsu Province 226112 China

CE 0197 EC REP SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

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