



Suresign Iron Deficiency Ferritin Test Cassette

(Fingerstick Whole Blood)

For Self-testing

REF OFE-402H

English

The Suresign Iron Deficiency Ferritin 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】

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}

【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 physician or medical professional.
- Follow the indicated time strictly. Alcohol pad to be used on unbroken skin only.
- 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 (36-86°F). The test is stable through the expiration date printed on the sealed test pouch. The test must remain in the sealed pouch. **DO NOT FREEZE.** Do not use beyond the expiration date.

【MATERIALS PROVIDED】

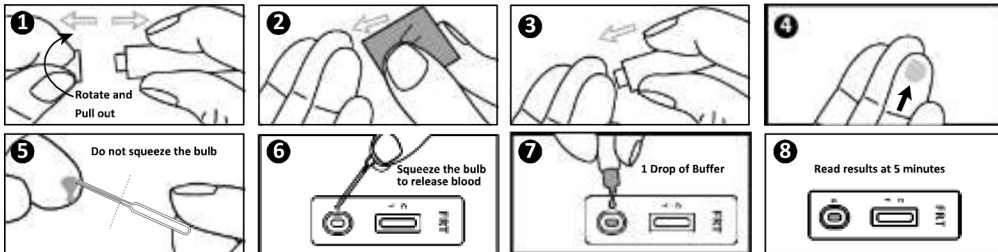
- Test cassette
- Capillary Dropper
- Buffer
- Alcohol pad
- Lancet
- Package insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer

【PROCEDURE】

- Wash your hands with soap and rinse with clear warm water.
- Bring the pouch to room temperature before opening it. Open the foil pouch and remove the cassette.
- Carefully pull off and dispose the released cap of the lancet.
- Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site. Allow to air dry.
- 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.
- Keeping the hand down massage the end of the finger that was pricked to obtain a blood drop.
- 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.
- Put the blood collected into the sample well of the cassette, by squeezing the dropper bulb.
- 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.
- Wait for the colored 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 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 your 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, discontinue using the test kit immediately and contact your local distributor.



Suresign Iron Deficiency Ferritin Test Cassette

(Fingerstick Whole Blood)

For Self-testing

REF OFE-402H

English

The Suresign Iron Deficiency Ferritin 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】

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}

【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 physician or medical professional.
- Follow the indicated time strictly. Alcohol pad to be used on unbroken skin only.
- 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 (36-86°F). The test is stable through the expiration date printed on the sealed test pouch. The test must remain in the sealed pouch. **DO NOT FREEZE.** Do not use beyond the expiration date.

【MATERIALS PROVIDED】

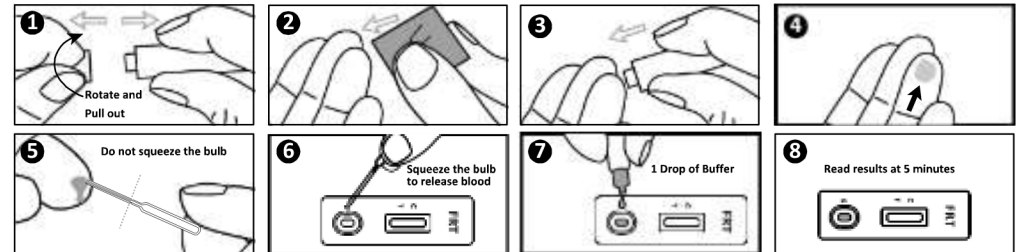
- Test cassette
- Capillary Dropper
- Buffer
- Alcohol pad
- Lancet
- Package insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer

【PROCEDURE】

- Wash your hands with soap and rinse with clear warm water.
- Bring the pouch to room temperature before opening it. Open the foil pouch and remove the cassette.
- Carefully pull off and dispose the released cap of the lancet.
- Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site. Allow to air dry.
- 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.
- Keeping the hand down massage the end of the finger that was pricked to obtain a blood drop.
- 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.
- Put the blood collected into the sample well of the cassette, by squeezing the dropper bulb.
- 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.
- Wait for the colored 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 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 your 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, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The Suresign Iron Deficiency Ferritin 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 finger stick 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 abnormal results are obtained.

【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 30ng/ml and a possible iron deficiency.

2. WHEN SHOULD THE TEST BE USED?

The Suresign Iron Deficiency Ferritin Test Cassette can be performed in cases 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 cases of disease, acute inflammations or in cases of spleen or liver injury. Abnormal results can be obtained even in cases of no iron deficiency situation.

3. CAN THE RESULT BE INCORRECT?

The results are accurate as long as the instructions are carefully carried out. 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 provides a "fill line" indicating the correct volume of blood to collect. Note, due to immunological principles involved, there exists the possibility of false results in rare cases. A consultation with a physician 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 been carried out as per the test instructions.

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 you should consult a physician, 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 Res1: 43-7.*

【LIMITATIONS】

1. The Suresign Iron Deficiency Ferritin 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 finger stick 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 abnormal results are obtained.

【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 30ng/ml and a possible iron deficiency.

2. WHEN SHOULD THE TEST BE USED?

The Suresign Iron Deficiency Ferritin Test Cassette can be performed in cases 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 cases of disease, acute inflammations or in cases of spleen or liver injury. Abnormal results can be obtained even in cases of no iron deficiency situation.

3. CAN THE RESULT BE INCORRECT?

The results are accurate as long as the instructions are carefully carried out. 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 provides a "fill line" indicating the correct volume of blood to collect. Note, due to immunological principles involved, there exists the possibility of false results in rare cases. A consultation with a physician 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 been carried out as per the test instructions.

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 you should consult a physician, 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 Res1: 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 # |

Hangzhou AllTest Biotech., Ltd
#550, Yin Hai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China



MedNet GmbH
Borkstrasse 10
48163 Muenster
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



Medpath GmbH
Mies-van-der-Rohe Strasse 880807
Munich, Germany

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



Shanghai International Holding Corp. GmbH(Europe)
Eiffestraße 80
20537 Hamburg
Germany

Lancet
 PROMISEMED MEDICAL DEVICE INC.
170 – 422 RICHARDS STREET
VANCOUVER BC V6B 2Z4, CANADA



Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands

Manufactured Under Licence & Distributed By:
CIGA Healthcare Ltd,
Kilcran House, Kildowney Road, Ballymena,
BT44 9EY, Northern Ireland.

REF: OFE-402H
PN: 00746A (SC-286A)
REV: 01/2022

Number: 146627900
Effective date: 2022-03-04

| 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 # |

Hangzhou AllTest Biotech., Ltd
#550, Yin Hai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China



MedNet GmbH
Borkstrasse 10
48163 Muenster
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



Medpath GmbH
Mies-van-der-Rohe Strasse 880807
Munich, Germany

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



Shanghai International Holding Corp. GmbH(Europe)
Eiffestraße 80
20537 Hamburg
Germany

Lancet
 PROMISEMED MEDICAL DEVICE INC.
170 – 422 RICHARDS STREET
VANCOUVER BC V6B 2Z4, CANADA



Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands

Manufactured Under Licence & Distributed By:
CIGA Healthcare Ltd,
Kilcran House, Kildowney Road, Ballymena,
BT44 9EY, Northern Ireland.

REF: OFE-402H
PN: 00746A (SC-286A)
REV: 01/2022

Number: 146627900
Effective date: 2022-03-04