**PHARMA** *SOUTHERN AFRICA*

# *FERRI-CHECK®*

***Ref. 25084/ZA***

## *Self-Diagnostic Test for the detection of iron deficiency in blood.*

## GENERAL POINTS

Anaemia due to iron depletion is widely held in children and women of all ages but mainly in women who still have their period (at least 20% suffer iron deficiency). Main signs as paleness, feeling tired, headaches, faster heartbeat or shortness of breath during exercise appear gradually and could go unnoticed. Therefore, it is important to determine if the available iron is sufficient for the body's needs.
Iron deficiency occurs when blood does not contain enough red cells and thus low levels of haemoglobin which is a major protein involved in oxygen transport in whole body. An important component of haemoglobin is iron. Depletion in iron, which can happen during pregnancy, growth, in case of insufficient iron intake, inadequate absorption or blood loss (periods, abnormal bleedings, ulcers…etc.) have tremendous effects on health.

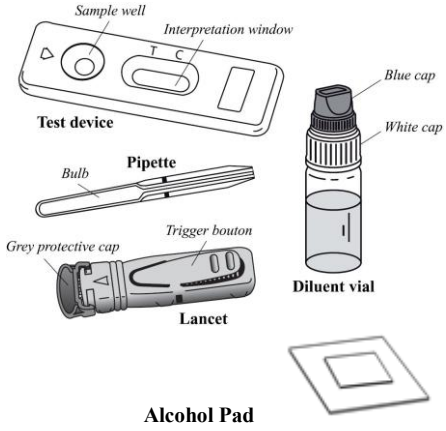
**Caution: This test is not appropriated for patient suspected of or suffering from hemochromatosis.**

The FERRI-CHECK® is a rapid immuno-diagnostic test for the assessment of ferritin (a protein capable of storing iron in cells) from finger prick whole blood sample. Therefore FERRI-CHECK® could be used for the screening of potential iron deficiency.

## PRESENTATION

The box contains all the material necessary to perform a test:
- **1 sealed aluminium pouch containing:**
  1 test device, 1 plastic pipette and 1 desiccant pouch.

Only open the protection pouch when you are ready to use the test. The desiccant bag should not be used.
- **1 sterile lancet for blood sampling.**
- **1 dropper bottle of 1 mL of diluent.** DIL
- **1 instruction manual.**
- **1 alcohol pad.**




Material required but not provided: Timer

## PRECAUTIONS

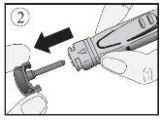
1. This test is exclusively intended for *in vitro* diagnostic use. External use only. DO NOT SWALLOW.
2. **Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.**
**Follow strictly the indicated time, blood and diluent quantities.**
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if this pouch is damaged.
5. Do not reuse the FERRI-CHECK®.
6. **Keep out of reach of children.**
7. After use, all components can be discarded in a dustbin.

## PROCEDURE

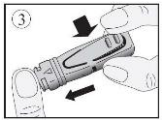
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

**1. Wash your hands thoroughly.** Use soap and warm water. Dry your hand with clean towel.

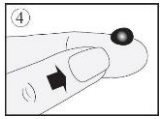
**2. Prepare the test device and the pipette**. Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant pouch.
3. **Prepare the lancet.** Hold the lancet **without touching the trigger button.** Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). **Don't pull just twist** and discard the cap when finished ① & ②.

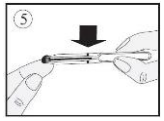

4. Clean the end of the middle finger or ring finger with the alcohol pad.
Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. **Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button**③.

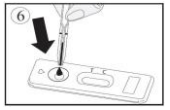



6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample ④.

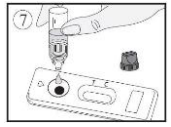



8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.




10. Wait 30-40 sec for the blood being totally absorbed into the sample well. **Unscrew the blue cap** of the diluent dropper vial (leave the white cap tightly screwed) and add the diluent as follows:
**Hold the diluent dropper vial vertically and slowly add exactly 4 drops in the sample well** of the device⑦ with an interval of 2-3 seconds between each drop.




11. Read the result within 10 minutes. Do not interpret after 15 minutes.

## RESULTS INTERPRETATION

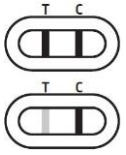
**The intensity and the colour of the lines do not have any importance for the interpretation of the test results.**

**1. Positive result**

Only one coloured line appears under the mark C (Control). This result means that the ferritin concentration in blood is too low. Reserves are insufficient. **You should consult a doctor because you may suffer of iron deficiency.**

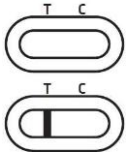

**2. Negative result**

Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be clearer than the intensity of the line C. This result means that the ferritin concentration in blood is normal and that there is no potential iron deficiency




**3. Invalid result**

No line appears or a coloured line appears under the mark T (Test) without any line under the mark C. In this case, it is not possible to interpret the test, which must be considered as invalid. It is recommended to repeat the test with a new FERRI-CHECK® device and a new blood sample.




## QUESTIONS AND ANSWERS

***How does FERRI-CHECK® work?***
FERRI-CHECK® uses a couple of antibodies detecting specifically ferritin by producing a coloured test line under the T mark of the cassette.
A control line capturing the reagent excess appears as a coloured line under the C mark of the cassette. In case only one line appears under the C mark, the test indicates that the level of ferritin is lower than normal (20 ng/mL determined against W.H.O.* reference).
***World Health Organisation***

***When should the test be performed?***
FERRI-CHECK® should be performed in case of symptoms like paleness, feeling tired, headaches, faster heartbeat or shortness of breath during exercise mainly when pregnant or in case of copious periods.
The test can be performed at any time of the day but must not be performed in case of diseases, acute inflammations or in case of spleen or liver injury. Positive results could be obtained even in case of no iron deficiency situation.

***Can the results be incorrect?***
**The results are accurate as long as the instructions are carefully respected.** Nevertheless, the results can be incorrect if FERRI-CHECK® gets wet before test performing or if the quantity of blood dispensed in the sample well is not correct. The plastic pipette provided in the box makes sure the collected blood volume is correct.

***How to interpret the test if the colour and the intensity of the lines are different?***
The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete. The test should be considered as negative regardless the colour intensity of the test line (T), even weak.

***What is the line that appears under the mark C (Control) for?***
When this line appears, it only means that the test has been performed well.

***If I read the result after 15 minutes, will the result be reliable?***
No. The result should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

***What do I have to do if the result is positive?***
If the result is positive, it means that the ferritin level in blood is lower than the norm (20 ng/mL) and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed.

***What do I have to do if the result is negative?***
If the result is negative, it means that the ferritin level is higher than 20 ng/mL and is within the norm. However, if the symptoms persist, it is recommended to consult a doctor.

***What is the accuracy of FERRI-CHECK®?***
The FERRI-CHECK® is accurate and has been used for more than 10 years by professionals in the field. Evaluation reports show an overall agreement higher than 98% [92.58 - 100**] with reference methods. Although this test is reliable, false positive or false negative results could be obtained.
***CI 95%: 95% Confidence Interval.**

Information on iron deficiency
https://www.doctissimo.fr/html/sante/analyses/ana_bilanmartial03.htm#
https://www.healthline.com/health/ferritin
https://www.mayoclinic.org/tests-procedures/ferritin-test/about/pac-20384928

**Sterile lancet:** STERILE R CE 1639

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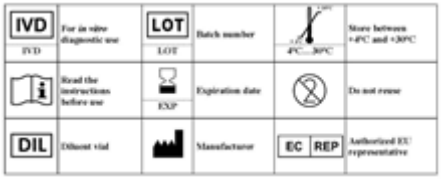


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CE 0483

**CHANGES DESCRIPTION**
Changes type :

- N/A Not Applicable (creation)
- Technical change Addition, revision and/or removal of information related to the product.
- Administrative Implementation of non-technical changes noticeable to the end-user.

| Changes type | Changes description |
|---|---|
| Administrative Change | Addition of alcohol pad in components and procedures |

**Note**: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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