

Prevention at home.

PRECAUTIONS

- 1) Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.
- 2) Keep out of the reach of children.
- 3) Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
- 4) Follow strictly the indicated time, blood and diluent quantities.
- 5) Store between +4°C and +30°C. Do not freeze.
- 6) Do not re-use the Iron Test - FER test device and lancet.
- 7) External use only. **DO NOT SWALLOW.**
- 8) This test is exclusively intended to in vitro diagnostic self-testing use.

REF 25084R

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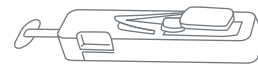
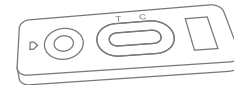
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CONTENT

THE BOX CONTAINS ALL THE NECESSARY TO PERFORM 1 IRON TEST - FER:

- 1 sealed aluminium pouch containing
 - 1 plastic pipette
 - 1 desiccant bag
 - 1 Test device
- 1 sterile lancet for blood sampling
- 1 dropper bottle containing 1 ml of diluent.
- 1 instructions leaflet



IRON TEST - FERRITIN

Easy to use rapid Self-Test for the determination of iron deficiency in blood

INSTRUCTIONS FOR USE

PRIMA[®] HOME TEST

IRON AND ANAEMIA

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 for iron deficiency). Main signs as paleness, feeling tired, headaches, faster heartbeat, or shortness of breath during exercise appear gradually and could go unnoticed.

Iron deficiency occurs when blood does not contain enough red cells and thus low levels of haemoglobin which is the major protein involved in oxygen transport in whole 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 tremendous effects on health.

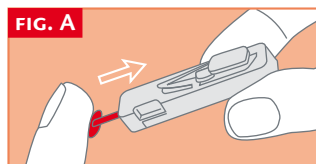
The Iron Test - FER is a rapid immunodiagnostic test for the assessment of ferritin (a protein capable of storing iron in cells) from finger prick whole blood sample. Therefore the Test can be used for the screening of potential iron deficiency.

- * Not provided necessary material: absorbent cotton and alcohol 70°
- * Only open the protective pouch when you are ready to use the test.
- * The desiccant bag should not be used.

PROCEDURE

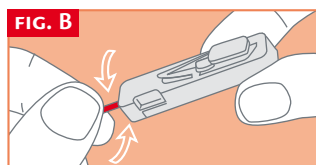
- 1) Wash your hands with soap and rinse with clear warm water.
- 2) Tear the protective pouch (from the notch) and only get out the device and the pipette. Dispose of the small desiccant bag.

- 3) Push the orange small rod into the body of the lancet until hearing a **CLICK** indicating the device is activated. - **FIG. A**



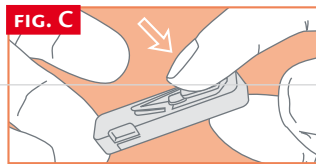
Be careful not to push the trigger because the needle can come out too early.

- 4) Remove the orange rod by turning it on the left or on the right. - **FIG. B**



- 5) Clean the end of the forefinger or of the middle finger with a cotton pad damped with alcohol. Massage the end of the finger, from the base of the finger to the end, to enhance the blood flow.

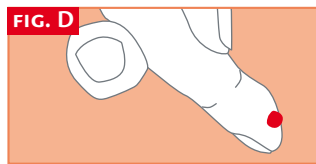
- 6) **Strongly press** the extremity of the lancet on the part of the finger which is cleaned with alcohol in order to obtain a very good contact.



Press on the trigger button. - **FIG. C**

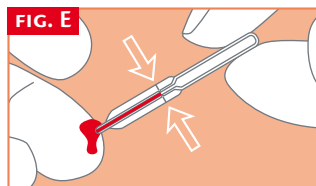
The tip retracts automatically and safely after use.

- 7) Keeping the hand down massage the end that was stung to obtain a blood drop. - **FIG. D**

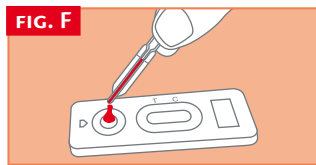


- 8) **Without pressing the pipette bulb**, put it in contact with the drop. - **FIG. E**

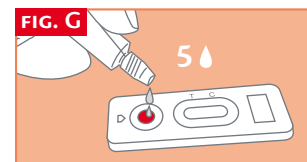
The blood migrates into the pipette through the capillarity to the line indicated on the pipette. You may massage again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.



- 9) Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb. - **FIG. F**



10) Wait for the blood totally being dispensed in the well. Using the dropper bottle, add **5 drops** of diluent into the sample well of the device - **FIG. G**



- 11) Read the result after **10 minutes**.

RESULT INTERPRETATION

**READ THE RESULT AFTER 10 MINUTES.
DO NOT READ THE RESULT AFTER 15 MINUTES.**

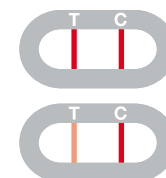
The intensity of the line colour does not have any importance for the interpretation of the test result.



NEGATIVE RESULT

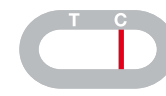
Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be clearer than the intensity of the line C.

This result means that the ferritin concentration in blood is normal and that there is no potential iron deficiency.



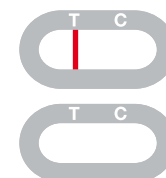
POSITIVE RESULT

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



NON VALID RESULT

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



F.A.Q. - QUESTIONS AND ANSWERS

HOW DOES THE IRON TEST WORK?

Ferritin is a protein and the primary form of iron stored inside cells. A positive result means that the ferritin concentration in blood is lower than 20 ng/mL and a possible iron deficiency.

WHEN SHOULD THE TEST BE USED ?

The Iron Test - FER 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 copious 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. Positive results can be obtained even in case of no iron deficiency situation.

CAN THE RESULT BE INCORRECT?

The results are accurate as far as the instructions are carefully respected.

Nevertheless, the result can be incorrect if the test gets wet before test performing or if the quantity of blood dispensed in the sample well is not sufficient, or if the number of diluent drops are less than 4 or more than 5.

The plastic pipette provided in the box allows making 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 clearly visible. The test should be considered as positive whatever the colour intensity of the test line is.

WHAT IS THE LINE THAT APPEARS UNDER THE MARK C (CONTROL) FOR?

When this line appears, it only means that the test was performing 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 is lower than the norm (20 ng/mL) and that you should consult the 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 THE IRON TEST - FER?

The Ferritin test is very accurate and has been used for more than 10 years by professionals in the field. Evaluation reports show an overall agreement of at least 98% with reference methods.

SYMBOLS

In vitro diagnostic device

Read the instructions before use

Store between +4°C and +30°C

Expiry date (last day of the months)

Do not reuse

List number

Lot number

Legal manufacturer

Lancet: **STERILE** **R** **CE**
0120

CE
0483
CERTIFIED