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Self-testing device for anaemia in whole blood (Ferritin) (at-home anaemia test)















Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

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IRON DEFICIENCY IN THE BLOOD

Iron deficiency occurs when blood does not contain enough red cells and thus has low levels of haemoglobin which is a major protein involved in transporting oxygen throughout the entire body. An important component of haemoglobin is iron. Iron deficiency 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 our health.

WHAT IS ANAEMIA DUE TO IRON DEFICIENCY IN THE BLOOD?

Anaemia due to iron deficiency is common in children and women of all ages but mainly in women who still have their period (at least 20% suffer from iron deficiency). The basic signs of anaemia can often go unnoticed. Therefore it is important to determine if the available iron is sufficient for the body's needs.

WHAT ARE THE SYMPTOMS?

Some of the most common symptoms are:

- Paleness
- Feeling tired
- Headache

- Faster heartbeat
- Shortness of breath during exercise



SELF-TESTING DEVICE FOR DETECTION OF IRON DEFICIENCY IN WHOLE BLOOD (at-home testing)

PURPOSE

Anaemia due to iron deficiency is common in children and women of all ages but mainly in women who still have their period (at least 20% suffer from 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 has low levels of haemoglobin which is a major protein involved in transporting oxygen throughout the entire 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 our health.

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



FAST AND RELIABLE RESULTS

Time: 10-15 minutes.

Store between +4°C and +30°C. Do not freeze!

1 test per box.

FERRI-Check® test uses a couple of antibodies specifically detecting ferritin by producing a coloured test line under the T mark of the test device. A control line capturing the reagent excess appears as a coloured line under the C mark of the test device. 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).

Easy to read.

The FERRI-Check test 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 occur.

CLINICAL EVALUATION RESULTS

Sensitivity: 100 % Specificity: 92.86 % Accuracy: 98.00 %



PROVIDED MATERIALS:

1 sealed aluminium pouch containing:

1 test device

1 plastic pipette

1 desiccant bag

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

1 sterlile lancet for blood sampling. 1 dropper bottle containing 1 mL of diluent. 1 instruction leaflet.

REQUIRED MATERIALS NOT PROVIDED:

Absorbent cotton and alcohol 70% vol. or alcohol pad.

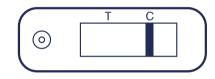




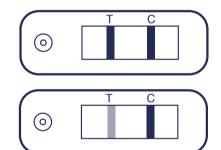
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows::

- 1. Wash your hands thoroughly. Use soap and warm water. Dry your hands with a clean towel.
- 2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them within reach of your hands (you will need them later). Discard the desiccant bag.
- 3. Prepare the lancet. Hold the lancet without touching the trigger button. Unlock the lancet cap twisting it $\frac{1}{4}$ of the way until you feel it separate from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished.
- 4.Clean the end of the middle finger or ring finger with cotton moistened with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
- 5. Press the platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button.
- 6. The tip will automatically retract into the body of the device.
- 7. Rub the finger's end to obtain enough whole blood sample.
- 8. Without pressing the blood drop that has formed, put the plastic pipette in contact with the blood sample. The blood migrates into the pipette through capillarity to the line indicated on the pipette. You may rub your finger again to obtain more blood if the line is not reached. Avoid air bubbles as much as possible.
- 9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb.
- 10. Wait 30-40 sec for the blood to be completely absorbed into the sample well. Unscrew the blue cap of the diluent dropper bottle (leave the white cap tightly screwed) and add the diluent as follows: Hold the diluent dropper bottle vertically and slowly add exactly 4 drops in the sample well of the device with an interval of 2-3 seconds between each drop.
- 11. Read the result after 10 minutes. Do not interpret after 15 minutes.

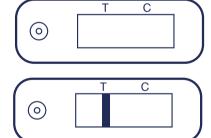




Positive: Only one coloured line appears under the mark C (Control). This result means that the ferritin concentration in the blood is too low. Reserves are insufficient. You should consult a doctor because you may suffer from iron deficiency.



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



Invalid: 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.

NOTE:

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



This test is exclusively intended for in vitro diagnostics use. External use only. DO NOT SWALLOW.

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.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.

Do not reuse the FERRI-Check® test.

Keep out of reach of children.

After use, all the components can be discarded in a dustbin.

Not suitable for children under 6 years old.

