

Iron deficiency

Rapid test for the detection of a low iron concentration

10 min



Accuracy > 95 %



Important for blood formation: the mineral iron

As a component of the red blood pigment, haemoglobin, iron plays an important role in supplying the body with oxygen and in energy metabolism. Typical signs for insufficient iron are frequent tiredness, paleness or headache. Intense heart palpitations or breathlessness after exertion are also possible symptoms. Approx. 2 out of 10 children and women of childbearing age are affected by iron deficiency.

Knowing where you stand: iron deficiency rapid test

The Iron deficiency rapid test enables you to find out in minutes whether your symptoms may be caused by iron deficiency and whether you need supplementary iron. Should this be the case, you can discuss how to proceed with your doctor.

How reliable is the Veroyal[®] test?

The Iron deficiency rapid test was developed for the purpose of making the accuracy and dependability of modern diagnostics also available for private use at home. It is based on the immunological detection of the protein ferritin in the blood, which stores iron in the cells. A positive result means that the ferritin concentration in the blood is below 20 ng/ml and there is a deficiency.

Accuracy, as evidenced by performance evaluation studies, is greater than 95 %.

Is the test complicated to perform?

No: All you need are clean washed hands, a clock and a flat table surface. The exact test procedure is described overleaf. It is necessary to read the instruction leaflet thoroughly to understand how the result is determined and interpreted. All details should be understood before performing the test.

Performance data:

	Reference test			
	Positive	Negative	Total	
Iron deficiency Rapid test	Positive	40	2	42
	Negative	1	63	64
Total	41	65	106	

Sensitivity: 97.56 % Specificity: 96.92 % Accuracy: 95.24 %

What should I pay attention to?

Warnings and important notes:

- The test is intended only for use outside the body.
- Do not consume any of the test components. Avoid skin and eye contact with the sample dilution buffer.
- Keep the test out of the reach of children.
- Do not expose the test to direct sunlight or frost. Do not freeze. Store in a dry place between 10 °C and 27 °C.
- The product may be used only until the imprinted expiry date.
- If the details of the instruction leaflet are not correctly followed, the test may produce false results.
- Do not use the test if the packaging is damaged. Do not use damaged test components.
- False-negative results* may occur in rare cases.
- All test components are intended only for use with this test. Do not re-use the test after use!
- The test should be performed immediately or within one hour after opening the foil bag.
- Poor eyesight, colour blindness or inadequate lighting can compromise the correct interpretation of the test.
- All test components can be discarded in the domestic waste.

Important information:

Positive test results may also occur for perfectly harmless reasons – negative results, however, do not always mean a complete all-clear. The final diagnosis should be made by a physician. To identify new risks promptly, regularly repeating the self-test for determining potential iron deficiency is recommended.

* False negative = a negative test result is wrongly displayed, even though the result is actually positive.

Materials

- 1 test cassette in foil bag
- 1 pipette
- 1 container with sample dilution buffer
- 2 automatic lancing devices (1 replacement) with sterile lancet for taking the blood sample



STERILE R CE 0120

- 1 glass capillary tube in protective container
- 1 alcohol swab



- 1 plaster



- 1 instruction leaflet

Explanation of symbols

Consult instruction leaflet	In vitro diagnostic product (for use outside the body)	Expiry date (see imprint on packaging)
Store in a dry place at 10°C–27°C. Do not freeze.	Contents sufficient for 1 test	Do not re-use
Manufacturer	Sterilised by irradiation	Batch number (see imprint on packaging)
Reaction time in the test cassette	Rapid test for self-testing	

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Iron deficiency Rapid test for self-testing This is how it's done:

1 • Lay out the test components on the table in front of you. At this stage, do not open the foil packaging.



- (1) Container with sample dilution buffer
- (2) Alcohol swab
- (3) Automatic lancing device
- (4) Glass capillary tube in protective container
- (5) Test cassette in foil bag
- (6) Pipette
- (7) Plaster

Preparation

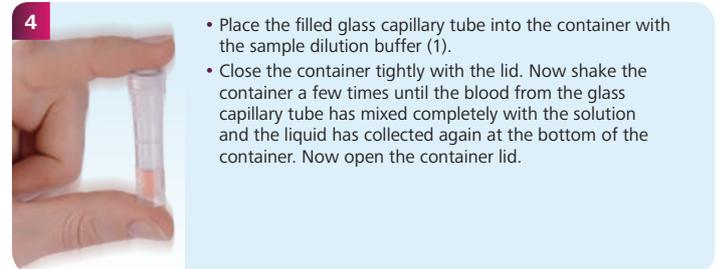
• Allow the test cassette and sample dilution buffer to reach room temperature before starting the test (15 °C to 27 °C). Open the container of the sample dilution buffer by removing the lid and place it upright on the table.



- Twist the grey cap of an automatic lancing device (3) until it detaches. Then twist fully another 2 times.
- Massage the tip of your index finger and clean with the alcohol swab (2). Allow your finger to dry.
- Press the lancing device with the round opening against the side of the clean fingertip (a) and activate the release mechanism (b).



- 3** • Open the protective container (4) and carefully remove the glass capillary tube.
- Squeeze a drop of blood from the fingertip.
- Hold the glass capillary tube horizontally into the drop of blood until it has filled completely.
- Use the enclosed plaster (7) if required.



- 4** • Place the filled glass capillary tube into the container with the sample dilution buffer (1).
- Close the container tightly with the lid. Now shake the container a few times until the blood from the glass capillary tube has mixed completely with the solution and the liquid has collected again at the bottom of the container. Now open the container lid.

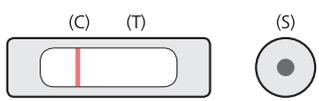
5 • Open the foil packaging shortly before use and lay the test cassette on a flat surface.



- 6** • Using the pipette (6), remove a few drops of the diluted sample.
- With the filled pipette (6), drop 3 drops from above into the round application field (S) of the test cassette (5). **Please ensure that no liquid is applied to the result window (T) or (C).** After applying the drops, do not touch or move the test cassette.
- **After adding the 3 drops, read off the result after exactly 10 minutes.**

To interpret the result, initially determine whether a line can be seen in the test window under (C). It is irrelevant how intense or faint the control line is.

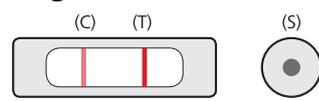
Positive result



The test result is **positive** if a light to dark red line appears in the control field (C) and **no red line** can be discerned in the test field (T).

This result means that the **iron concentration in the blood is too low**. The iron reserves are insufficient. Please consult a physician, as you could be suffering from iron deficiency.

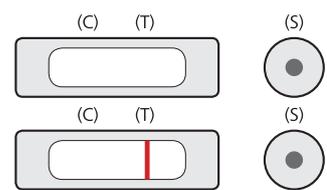
Negative result



The test result is **negative** if a light to dark red line appears in the control field (C) and a light or dark red line can be discerned in the test field (T).

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

Invalid result



If you **do not see a control line (C) or see only a test line (T)**, the test did not proceed correctly and is invalid.

Check whether you have followed all points of the instruction leaflet exactly. Perform a new test with a new blood sample.