FerritinCHECK©

Tired? Headache? Susceptible to infections?
Rapid test for the detection of iron deficiency

INSTRUCTIONS FOR USE

For self-testing

INTRODUCTION

Iron deficiency is caused by insufficient dietary intake and absorption of iron, or iron loss from bleeding (for example, menstrual bleeding, abnormal bleeding or ulcers), also during pregnancy or growth phase, and has serious health consequences.

Fatigue, headache, pallor, strong heartbeats or shortness of breath are all possible indications of an iron deficiency.

Iron deficiency prevalence is highest among young children and women of childbearing age. It is important that current body iron stores are sufficient. Iron is stored a protein complex called Ferritin. Hence, Ferritin in the human blood serum is a laboratory marker of the total amount of iron stored in the body.

FerritinCHECK© is intended as an aid in the detection of iron deficiency. When the blood sample is mixed with the sample dilution buffer and applied to the sample well, it reacts with the specific anti-Ferritin antibodies coated gold particles. The mixture migrates along the membrane through capillary force. Once the mixture with coated particles reaches the test region, it will be captured by the specific anti-Ferritin antibodies immobilized on the membrane in the test line region, forming a color line. The presence of a colored line in the test position (T) indicates a negative result (no iron deficiency). The final diagnosis must be confirmed by the physician.

An explanation of how to read and interpret the test result is given in the instruction pamphlet. Therefore, it is important to fully understand the entire instruction pamphlet before performing the test.

A **step-by-step instruction** is given at the **opposite side** to facilitate the test performance. However, it does not replace the general instructions for use.

TEST CONTENTS

- 1 test cassette (Ferritin) in a sealed pouch
- 1 pipette
- 1 glass capillary tube in a protective container
- 1 solution bottle with sample dilution buffer
- 1 automatic sterile lancet

Owen Mumford Ltd.
Brook Hill, Woodstock
Oxfordshire, OX20 1TU, UK
CE 1639 STERILE R

EC REP Owen Mumford GmbH, Alte Häge 1, 63762 Großostheim

- 1 alcohol pad
- 1 plaster

Paul Hartmann AG
89522 Heidenheim, Germany
CE

- 1 instruction for use

Additionally required:

- 1 timer

TEST PREPARATION

Let test cassette and solution bottle stand at a room temperature (15°C to 27°C) before performing the test. Open the solution bottle with the sample dilution buffer by screwing the cap and let it stand upright on a table.

TEST PERFORMANCE

Read the instructions for use **completely** before performing the test.

A **step-by-step instruction** is given on the **next page** and describes the test procedure.

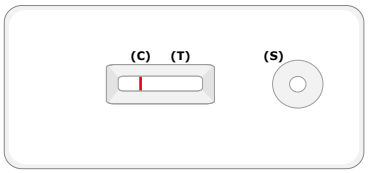
EVALUATION OF TEST RESULTS

To read the test results simply determine whether a line is present or absent at the control (C) position. It does not matter how strong or weak a Control line (C) is.

POSITIVE TEST RESULT

If there is **only Control line (C) and NO Test line (T)**, the test result is positive.

The test result means that the **Ferritin concentration and thus the iron concentration in your blood is low**. Please consult a physician, as you could suffer from iron deficiency.

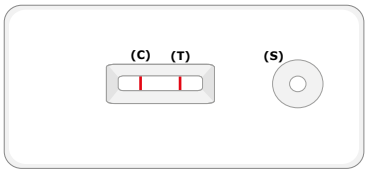


NEGATIVE TEST RESULT

If there are any line at all at the **Control (C) position and the Test (T) position**, the test result is negative.

The test result means that the **Ferritin concentration and thus the iron concentration in your blood is considered normal** and there is no iron deficiency.

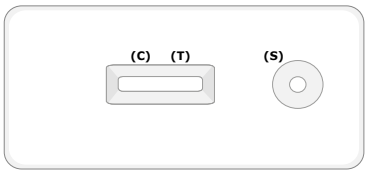
An acute infection or inflammation, as well as a disease of the liver, spleen or kidney, can increase the ferritin level. If there are any symptoms, please visit a physician for further medical investigation.

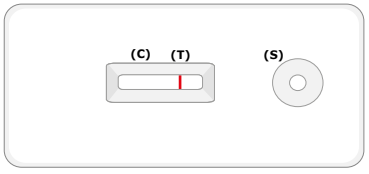


INVALID TEST RESULT

If there is **no Control line (C) or only a Test line (T)** in the result window, the test did not run correctly and the results are not valid.

It is important that you carefully followed the instructions for the test. You should test again with a new blood sample and a new test.





PERFORMANCE EVALUATION

		Reference Test		
		Positive	Negative	Total
Ferritin CHECK	Positive	40	2	42
	Negative	1	63	64
	Total	41	65	**106**

Sensitivity: 97.56%
Spezificity: 96.92%
Accuracy: 95.24%
Trueness: 97,17%

WARNINGS AND IMPORTANT INFORMATION

- The test is intended for use outside the body.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes. Keep out of the reach of children.
- Protect from sunlight, do not freeze. Store in a dry place between 10°C und 27°C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by the physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- False negative test result occurs rarely.
- All test components are intended for this test only. Do not reuse the test or test components.
- The test should be performed immediately or within one hour after opening the foil pouch.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- All test components can be disposed in household waste
- The test may only be performed by non-pregnant adult users.

BIOLOGICAL REFERENCE RANGE AND LITERATURE

Ferritin levels in healthy people are usually between 15 ng and 300 ng/mL. FerritinCHECK detects a Ferritin concentration of 20 ng/mL and higher with a negative result (no iron deficiency).

1. WHO. Serum ferritin concentrations for the assessment of iron status and iron deficiency in populations. Vitamin and Mineral Nutrition Information System. Geneva, World Health Organization, 2011

2. Percy L, Mansour D. Iron deficiency and iron-deficiency anaemiain women's health. The Obstetrician & Gynaecologist. 2017;19:155–61.

For further information regarding the biological reference range or literature, please contact the manufacturer.

Explanation of symbols:

Follow instructions	IVD In vitro diagnostic medical device (for external use)	Best before (See imprint on package)
10°C - 27°C Store at 10°C - 27°C DO NOT FREEZE	Σ 1 Content sufficent for 1 test	2 Do not reuse
Manufacturer	STERILE R Sterilization by irradiation	LOT Batchnumber (See imprint on package)
REF Reference number	EC REP Authorised Representative	

CE 0483

Instructions English
Revision from 2021-06 (Rev. 05)

REF: 360100

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For the love of life.

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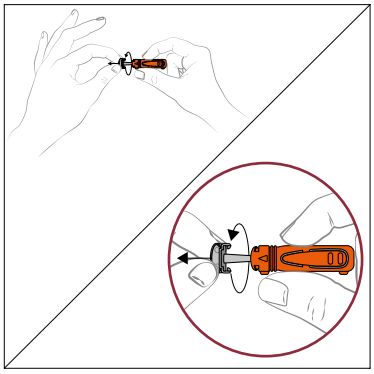
STEP-BY-STEP INSTRUCTION

For self-testing

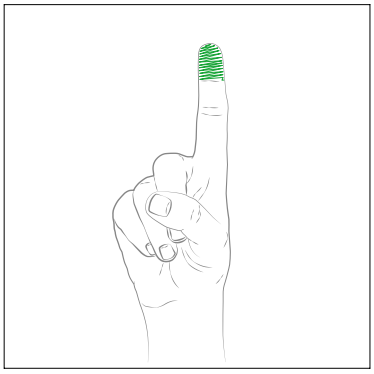
STEP 1



Please note: The lancing device can only be triggered once.

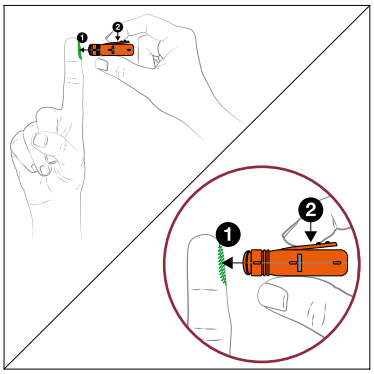
Twist the grey cap on the automatic lancet until the cap separates easily from the lancet body. **Then twist it at least two more times** before removing the cap, otherwise the proper function can not be ensured.

STEP 2



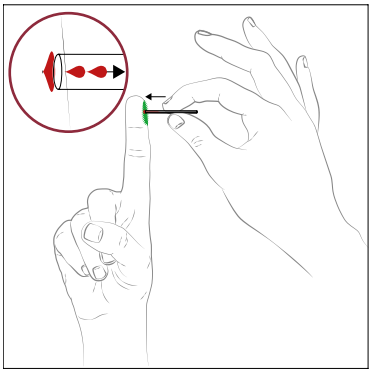
Slowly massage your fingertip and clean it using the alcohol pad. Wait until the fingertip is dry, as residual alcohol can interfere with the test result.

STEP 3



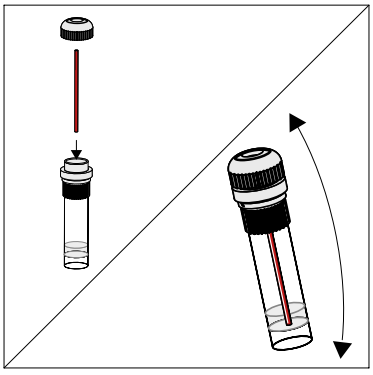
Press the automatic lancing device with the round opening firmly against the clean fingertip ❶ and activate it by pushing the button ❷ The puncture is almost painless.

STEP 4



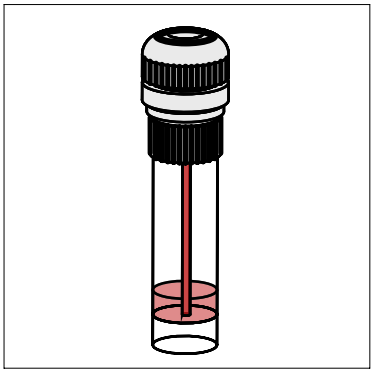
Open the plastic container and carefully remove the glass capillary tube. Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally against the blood drop on the finger until it has completely filled.

STEP 5



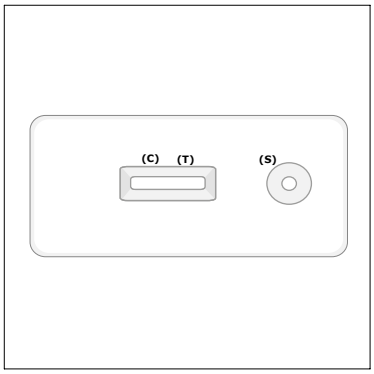
Insert the filled glass capillary into the solution bottle and screw the cap back. Mix the content of the solution bottle by turning it gently upside down several times until the blood from the glass capillary tube is mixed with the solution.

STEP 6



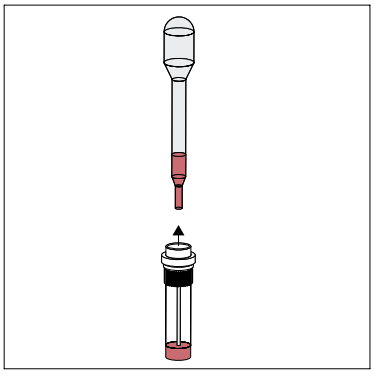
Before twisting off the cap, let the sample mixture settle back to the bottom of the solution bottle. Only then twist off the cap.

STEP 7



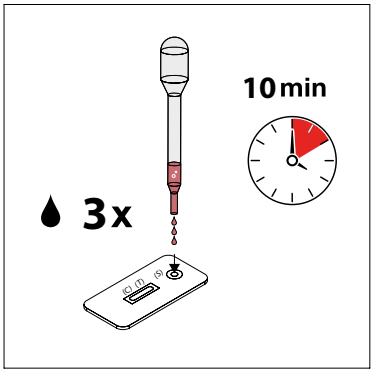
Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

STEP 8



Use the pipette to remove a few drops of the diluted sample.

STEP 9

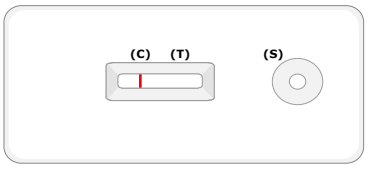


Hold the pipette with the sample mixture straight over the test cassette and squeeze gently to add exactly 3 drops to the sample well (S). **Please note that there should be no liquid applied to the result windows marked with the letters (T) and (C).** Do not touch or move the test cassette after adding the drops to the sample well (S).

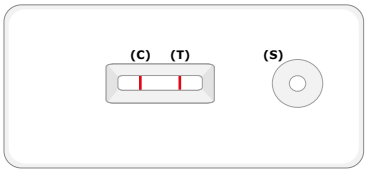
Read the result 10-15 minutes after adding the sample. Low values may be missed before the 10 minutes have elapsed, and false positive results may occur after more than 15 minutes.

TEST RESULT

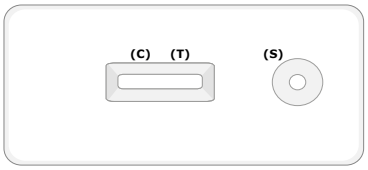
POSITIVE TEST RESULT

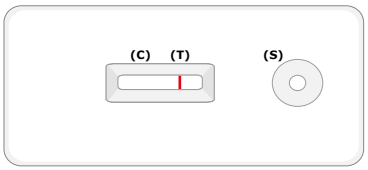


NEGATIVE TEST RESULT



INVALID TEST RESULT





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