

FerritinCHECK®

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

For self-testing

INSTRUCTIONS FOR USE

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 in protein complex as 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 diagnosis 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 action. 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 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 0120 **STERILE R**
- 1 alcohol pad
 - 1 plaster
 - 1 instruction pamphlet
- Paul Hartmann AG
89522 Heidenheim, Germany
- CE

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

1. Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two times again.
2. Slowly massage your fingertip and clean it using the alcohol pad. Wait until the fingertip is dry.

3. Press the automatic lancing device with the round opening firmly against the clean fingertip and activate it by pushing the button. The puncture is almost painless.
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 until it has completely filled.
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.
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.
7. Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.
8. Insert the pipette into the solution bottle and add a few drops of the sample mixture.
9. Hold the pipette with the sample mixture straight up and down 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).**

Please wait exactly 10 minutes after adding 3 drops to the sample well! Then read the result.

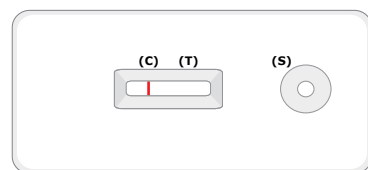
EVALUATION OF TEST RESULTS

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.

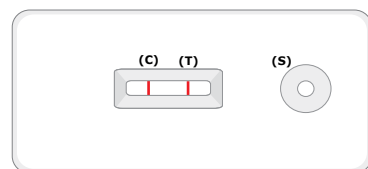
The test result means that the **iron concentration in your blood is low**. Iron reserve is inadequate. You should see a doctor to diagnose the iron deficiency.



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.

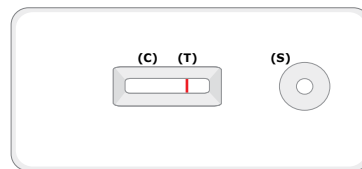
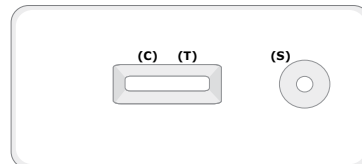
The test result means that the **iron concentration in your blood is considered normal** and there is no iron deficiency.



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% Specificity: 96,92%
Accuracy: 95,24%

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 and 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.

Explanation of symbols:

Follow instructions	In vitro diagnostic medical device (for external use)	Best before (See imprint on package)
Store at 10°C - 27°C DO NOT FREEZE	Content sufficient for 1 test	Do not reuse
Manufacturer	Sterilization by irradiation	Lot number (See imprint on package)

CE 0483
Instructions English
Revision from 2016-06 (Rev. 00)



NanoRepro AG
Untergasse 8
D-35037 Marburg
www.nano.ag



For the love of life.

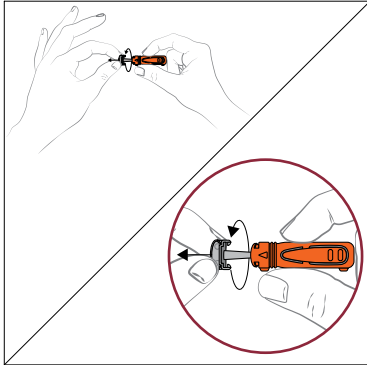
FerritinCHECK[®]

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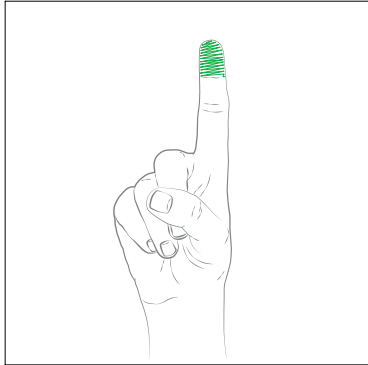
STEP-BY-STEP INSTRUCTION

STEP 1



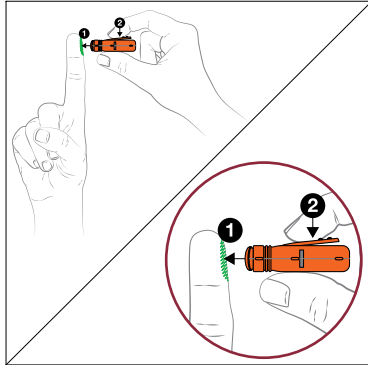
Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two times again.

STEP 2



Slowly massage your fingertip and clean it using the alcohol pad. Wait until the fingertip is dry.

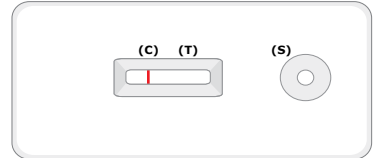
STEP 3



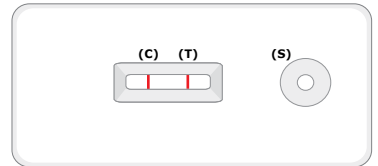
Press the automatic lancing device with the round opening firmly against the clean fingertip ① and activate it by pushing the button ②. The puncture is almost painless.

TEST RESULT

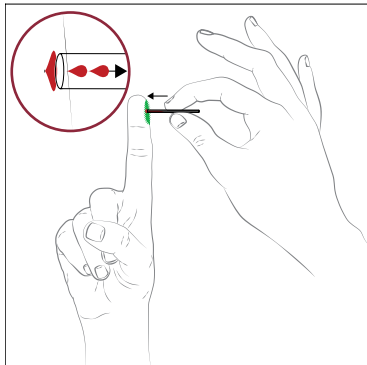
POSITIVE TEST RESULT



NEGATIVE TEST RESULT

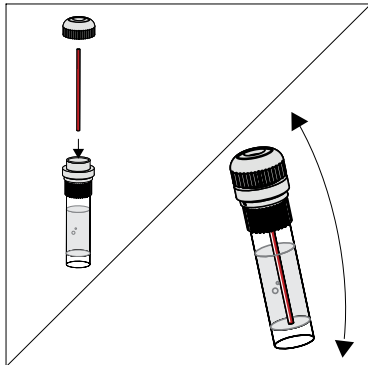


STEP 4



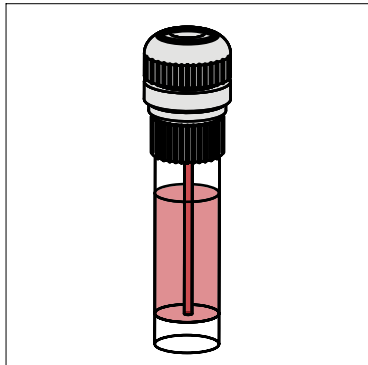
Open the plastic container and carefully remove the glass capillary tube. Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally until it has completely filled.

STEP 5



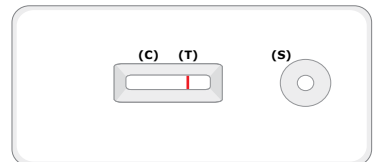
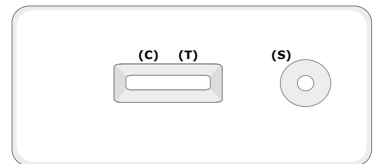
Insert the filled glass capillary into the solution bottle and screw the cap back. Mix the content of the solution bottle by turning it gently upside down several times until the blood from the glass capillary tube is mixed with the solution.

STEP 6

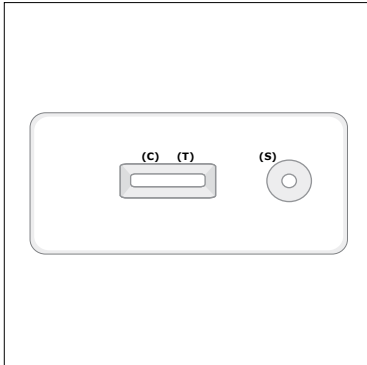


Before twisting off the cap, let the sample mixture settle back to the bottom of the solution bottle. Only then twist off the cap.

INVALID TEST RESULT

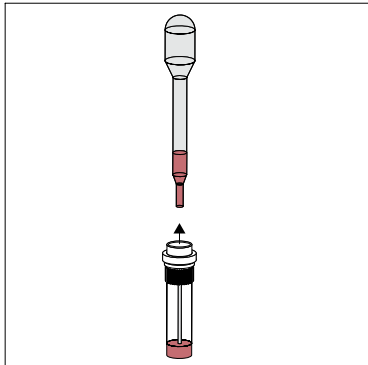


STEP 7



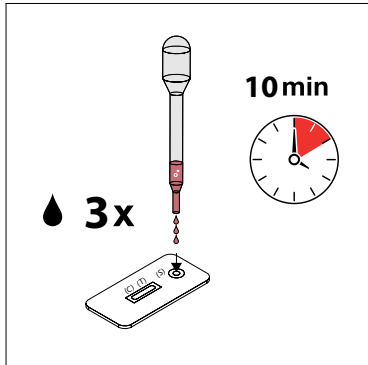
Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

STEP 8



Insert the pipette into the solution bottle and add a few drops of the sample mixture.

STEP 9



Hold the pipette with the sample mixture straight up and down 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). Please wait exactly 10 minutes after adding 3 drops to the sample well!! Then read the result.



For the love of life.