TSH CHECK©

Tired? Listless? Weight gain?

Rapid test for the detection of hypothyroidism

INSTRUCTIONS FOR USE

For self-testing

INTRODUCTION

The thyroid plays a central role in the control of the metabolism. Malfunctions can therewith influence the whole body. To detect hyper- or hypofunctions, in particular the level of thyrotropin, the thyroid stimulating hormone (TSH) is a reliable indicator. TSH gets secreted by the pituitary gland and stimulates the thyroid to produce the hormones T3 and T4. Whenever the concentration of the thyroid hormones T3 and T4 drops, TSH levels rise.

The symptoms of a thyroid hypofunction include, amongst others, fatigue, listlessness, feeling of coldness, constipation, muscle cramps or weight gain.

TSH CHECK© assesses whether TSH levels are elevated. A normal TSH concentration ranges from 0.4 µIU/ml to 4.5 µIU/ml while a value of >5 µIU/ml indicates a thyroid hypofunction. If the test shows a positive result, one can assume that the TSH concentration is above normal values indicating a thyroid hypofunction. The definitive diagnosis should be confirmed by a physician.

As an immunochromatographic rapid test for self-testing, **TSH CHECK©** detects an elevated TSH level in a sample of whole blood. If the TSH concentration is increased, it binds the antibodies immobilized on the test membrane. The visualization takes place through additional binding of colloidal gold labelled anti-TSH-antibodies that form a visible red test line (T-line).

Furthermore, the test includes a built-in control system realized by a red control line (C-line). The C-line confirms a sufficient amount of sample volume as well as a correct performance of the test.

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

TEST CONTENTS

- 1 test cassette (TSH, 5 µIU/ml) in a sealed pouch
- 1 pipette
- 1 glass capillary tube in a protective container
- 1 solution bottle with sample dilution buffer
- 1 automatic lancing device with sterile lancet for blood sampling
  Owen Mumford Ltd.
  Brook Hill, Woodstock
  Oxfordshire, OX20 1TU, UK
  CE 0120 STERILE R
- 1 alcohol pad
  Paul Hartmann AG
  89522 Heidenheim, Germany
  CE
- 1 plaster
  Paul Hartmann AG
  89522 Heidenheim, Germany
  CE
- 1 instructions for use

Additionally required:

- 1 timer

TEST PREPARATION

Warm test cassette and sample dilution buffer to room temperature (15 °C to 27 °C) before performing the test. Have a timer ready for time recording.

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.

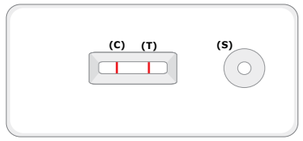
EVALUATION OF THE TEST RESULTS

To evaluate the test results, firstly you have to determine whether a line is present or absent at the control position (C). It does not matter how strong or faint the control line (C) appears.

POSITIVE TEST RESULT

If a faint red to dark red **control line (C)** is visible in the result window **along with** a faint red to dark red **test line (T)**, the test result is **positive.**

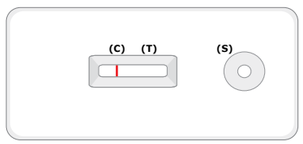
This result indicates a TSH concentration in your blood sample of more than 5 µIU/ml. It might indicate a hypofunction of the thyroid (hypothyroidism). In case of a positive test result, we advise you to consult your physician.



NEGATIVE TEST RESULT

If a faint red to dark red **control line (C) but no** faint red to dark red **test line (T)** is visible in the result window, the test result is **negative**.

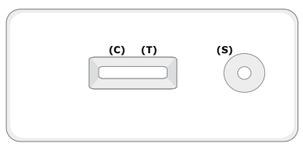
This result indicates a TSH concentration in your blood sample of less than 5 µIU/ml. The probability for a hypofunction of the thyroid (hypothyroidism) is low. In case of persisting symptoms or complaints, we advise you to consult a physician.

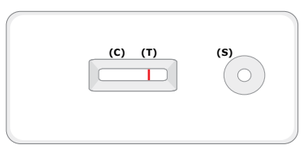


INVALID TEST RESULT

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

Make sure that you carefully followed all the steps of the instructions for use. You should test again with a new blood sample and a new test.





PERFORMANCE EVALUATION

		Reference Test		
		Positive	Negative	**Total**
TSH CHECK	Positive	27	2	29
	Negative	1	40	41
	Total	28	42	**70**

Sensitivity: 96,43 % Specificity: 95,24 %
Trueness: 93,10 % Accuracy: 95,71 %

WARNINGS AND IMPORTANT INFORMATION

- The test is intended for use outside the body only.
- Not to be taken internally. Avoid contact of sample dilution buffer with skin and eyes.
- Keep out of reach of children.
- Protect from direct sunlight, do not freeze. Store in a dry place between 2 °C and 30 °C.
- Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. False-positive or false-negative results might occur in few cases. The definitive diagnosis must be confirmed by a physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components!
- The test should be performed immediately after opening the sealed pouch.
- Poor vision, color blindness or poor lightning may affect your ability to interpret the test correctly.
- All test components can be disposed of in the household waste.
- Persons over 60 years old are likely to have an elevated TSH level without presence of hypothyroid symptoms. Please consult a physician for further evaluation.
- During pregnancy, TSH levels are likely to be elevated. If you detect a TSH value above 5 µIU/ml, we advise you to discuss the result with a physician.

BIOLOGICAL REFERENCE RANGE AND LITERATURE

Normal TSH concentrations range from 0.4 µIU/ml to 4.5 µIU/ml, while a value of >5 µIU/ml indicates a hypofunction of the thyroid (hypothyroidism).

1. Biondi 2013-J Clin Endocrinol Metab, Sept, 98(9):3584–3587

2. Lewandowski 2015-Thyroid Research 2015 8(Suppl 1):A17

3. McNeil and Stanford 2015-Clin Biochem Rev 36 (4)

Please contact the manufacturer for further information regarding the biological reference range and supplementary literature.

Explanation of symbols

Follow instructions for use	IVD In vitro diagnostic medical device (for external use)	Verwendbar bis (siehe Aufdruck Packung)
30°C 2°C Store at 2-30 °C, DO NOT FREEZE	Σ 1 Content sufficient for 1 test	2 Do not reuse
Manufacturer	STERILE R Sterilization by irradiation	LOT Batch number (See imprint on package)
REF Reference number		

REF: 780000

CE 0483

Instructions English
Revision from 2018-02 (Rev. 01)

NanoRepro AG
Untergasse 8
D-35037 Marburg
www.nanorepro.com

For the love of life.

TSH CHECK©

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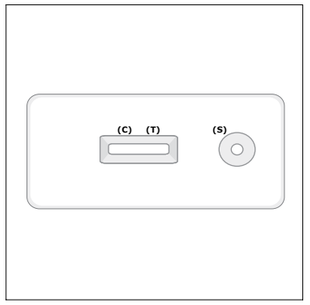
Rapid test for the detection of hypothyroidism

STEP-BY-STEP INSTRUCTION

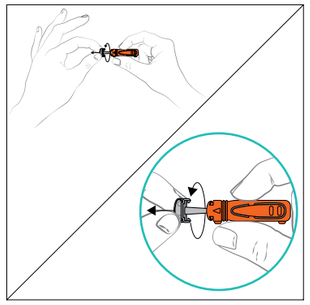
For self-testing

STEP 1



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

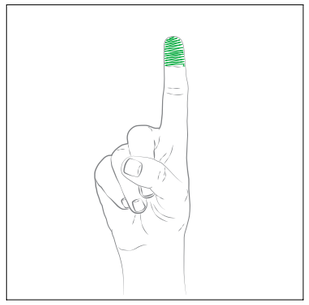
STEP 2



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

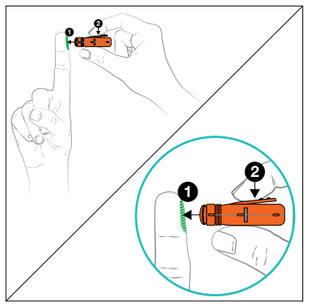
Twist the gray cap of the automatic lancing device **until** the cap separates easily from the lancing device body. **Then twist it at least two more times** before removing the cap. Otherwise, the proper function cannot be ensured.

STEP 3



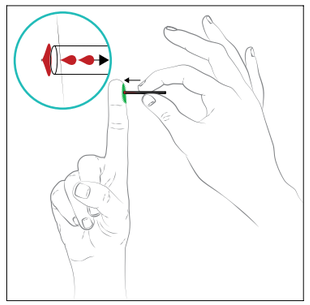
Slowly massage your fingertip and clean it using the alcohol pad. Wait until the fingertip is dry, as residual alcohol can interfere with the test result.

STEP 4



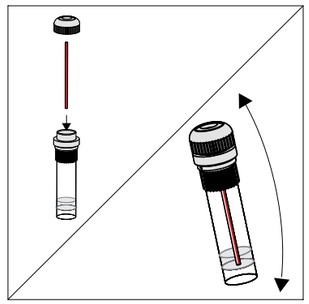
Press the automatic lancing device with the round opening firmly against the clean fingertip ❶ and activate it by pushing the button ❷. Massage the fingertip so a drop of blood can form, without directly touching the puncture site.

STEP 5



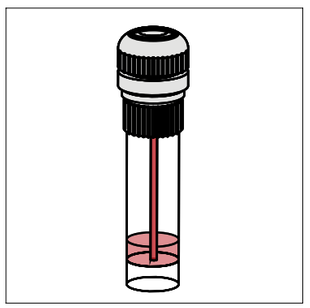
Open the protective container and carefully remove the glass capillary tube. Squeeze a drop of blood out of the fingertip. Hold the glass capillary tube horizontally against the drop of blood on the finger until it has completely filled up. Use the included plaster according to your need.

STEP 6



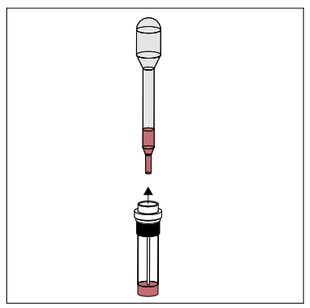
Insert the filled glass capillary tube into the solution bottle with sample dilution buffer and screw the cap back on tightly. Mix the content of the solution bottle by turning it gently upside down several times until the blood from the glass capillary tube is mixed with the solution entirely.

STEP 7



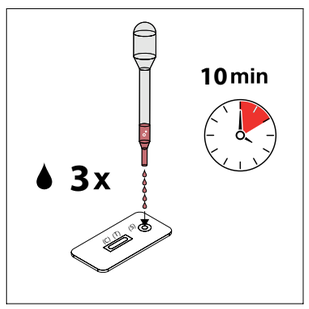
Before twisting off the cap, let the sample mixture settle back to the bottom of the solution bottle. Only then unscrew the cap.

STEP 8



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

STEP 9

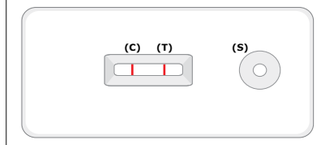


Hold the pipette with the sample mixture straight over the test cassette and squeeze gently to add **exactly 3 drops** to the sample well (S). **Please note, that there should be no liquid applied to the result window marked with the letters (T) and (C).** Do not touch or move the test cassette after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

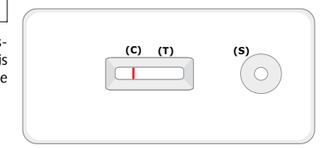
After adding the 3 drops to the sample well, read the result after 10 minutes. After more than 15 minutes false-positive results may occur.

TEST RESULT

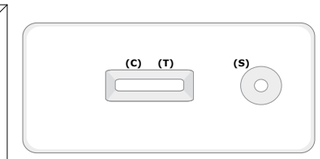
POSITIVE

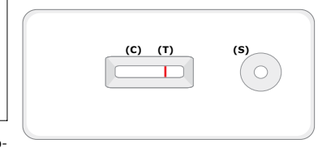


NEGATIVE



INVALID





We would be pleased to receive your feedback about our product. To do so, you are welcome to use the evaluation form on our web page.

www.zuhausetest.de

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