**INSTRUCTIONS FOR USE**

**INTRODUCTION**

The thyroid plays a central role in the control of the metabolism. Malfunctions can then influence the whole body. To detect hyper- or hypofunctions, in particular the level of thyroxin, 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 sadness, 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 hyperfunction. 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 labeling of colloidal gold labelled anti-TSH-antibodies that form a visible red test line (T-line). Furthermore, the test includes a control line (C-line) for checking if the test cassette is functioning correctly.

**EvAluATion of ThE TEST rESuLTS**

To evaluate the test results, firstly you have to determine whether a line is present or absent. If the control line (C) is visible, the result is positive. If there is no control line (C) or only a test line (T) visible in the result window, the test result is negative.

**sYMBoLS**

- (C) (T): Positive test result
- (C): Negative test result
- (C): Invalid test result

**MANuFACTuRER**

NanoRepro AG Untergasse 8 74613 Heidenheim, Germany

**LITERATURE**

1. Biondi 2013-J Clin Endocrinol Metab, Sept, 98(9):3664-3667
2. Lewandowski 2015-Thyroid Research 2015 RevSuppl 1:13-17

**PERFORMANCE EVALUATION**

For self-testing

**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.

**BIOLOGICAL REFERENCE RANGE AND LIMITING VALUES**

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

1. Bischof 2013 - Clin Endocrinol Metab, Sept, 98(9):3664-3667
2. Lewandowski 2015 - Thyroid Research 2015 RevSuppl 1:13-17

**INSTRUCtIONS FOR USE**

For self-testing

**INFORMATION**

- For the discussed result, we advise you to consult your physician.
- Only use test components!
- All test components are only intended to be used once.
- The test is intended for use outside the body (IVD).
- Not to be taken internally. Avoid contact of test components!
- All test components can be disposed of in accordance with your local regulations.
- We would be pleased to receive your feedback about our product. To do so, please use the evaluation form on our web page.

**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
- 1 alcohol pad
- 1 plaster
- 1 lancet (NanoRepro AG, Germany)

**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.

**PERFORMANCE EVALUATION**

<table>
<thead>
<tr>
<th>Reference Test</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>% Recall</th>
<th>% Specificity</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSH CHECK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WARNINGs AND IMPORTANT INFORMATION**

- Please consult the manufacturer for further information regarding the biological reference range and supplementary literature.
- All test components can be disposed of in accordance with your local regulations.
- Not to be taken internally. Avoid contact of test components!

**TEST REsULT**

**POsITIVE**

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

**NEGATIVe**

- Insert the filed 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 up and down several times until the blood from the glass capillary tube is mixed with the solution entirely.

**INVAlid**

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

**TSH CHECK®** Rapid test for the detection of hypothyroidism

**INSTRUCTIONS FOR USE**

For self-testing

**STEP-BY-STEP INSTRUCTION**

**STEP 1**

- Open the waisted 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**

- 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.

**STEP 4**

- 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 5**

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

**STEP 6**

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

**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**

- Hold the pipette with the sample mixture straight over the test cassette and squeeze gently. You will notice that there is a small droplet of liquid applied to the result window with the letters (C) and (T). Do not touch or move the test cassette after applying the droplets to the sample well (T).

**STEP 9**

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