

THYRO-CHECK®

Ref. 21084/ZA

Self Diagnostic Test for the detection of under active thyroid in blood

GENERAL POINTS

Thyroid disorders are one of the most prevalent medical conditions in the world, particularly for women, with an increasing rate of the population suffering under active thyroid (hypothyroidism). The symptoms of hypothyroidism include feeling tired and lethargic, weight gain, dry skin and brittle hair, becoming forgetful and sometimes depressed, feeling cold and enduring constipation as well as menstrual irregularities in women. Thyroid stimulating hormone (TSH), which is secreted by pituitary, regulates and controls the activity of the thyroid gland. Therefore, a raised TSH level indicates an under active thyroid and this is the principle on which THYRO-CHECK® is based for the detection of the hypothyroidism condition.

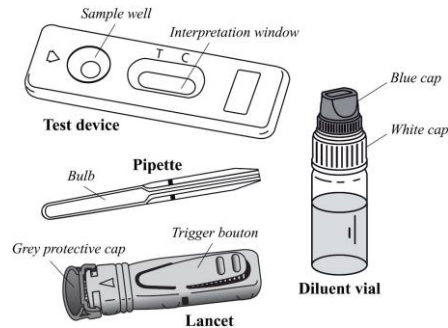
Caution: THYRO-CHECK® should not be performed in case of hormonal thyroid medical treatment.

THYRO-CHECK® is a rapid immunodiagnostic test for the detection of increased TSH levels and therefore for hypothyroidism screening from a finger prick blood sample.

PRESENTATION

The box contains the material necessary to perform a test:

- **1 sealed aluminium pouch** containing:
1 test device, 1 plastic pipette and 1 desiccant bag.
- Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.
- **1 sterile lancet for blood sampling.**
- **1 dropper bottle containing 1 mL of diluent.**
- **1 instruction leaflet.**



Not provided necessary material: absorbent cotton and alcohol 70 % vol. or alcohol pad.

PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic. External use only. DO NOT SWALLOW.
2. **Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected. Follow strictly the indicated time, blood and diluent quantities.**
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
5. Do not re-use THYRO-CHECK®.
6. **Keep out of the reach of children.**
7. After use, all components can be discarded in a dustbin.

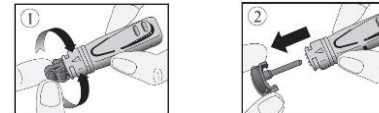
PROCEDURE

Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

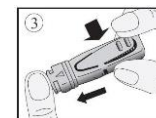
1. **Wash your hands thoroughly.** Use soap and warm water. Dry your hand with clean towel.



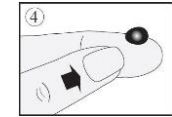
2. **Prepare the test device and the pipette.** Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag.
3. **Prepare the lancet.** Hold the lancet without touching the trigger button. Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished ① & ②.



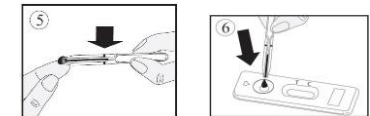
4. Clean the end of the middle finger or ring finger with cotton damped with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. **Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button ③.**



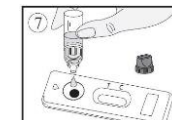
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.④.



8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.



10. Wait 30-40 sec for the blood being totally absorbed into the sample well. Unscrew the blue cap of the diluent dropper bottle (leave the white cap tightly screwed) and add the diluent as follows: **Hold the diluent dropper bottle vertically and slowly add exactly 4 drops in the sample well**⑦ with an interval of 2-3 seconds between each drop.



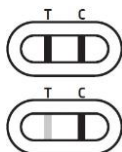
11. Read the result after 10 minutes. Do not interpret after 15 minutes.

RESULTS INTERPRETATION

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

1. Positive result

Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be clearer than the intensity of the line C. This result means that the TSH level is higher than the norm and therefore a dysfunction of the thyroid so **you should consult a doctor.**



2. Negative result

Only one coloured line appears under the mark C (Control). This result means that the TSH level is normal and the thyroid is functioning correctly.



3. Invalid result

No line appears or a coloured line appears under the mark T (Test) without any line under the mark C (Control). In this case, it is not possible to interpret the test, which must be considered as invalid. It is recommended to repeat the test with another THYRO-CHECK® and a new blood sample.



QUESTIONS AND ANSWERS

How does THYRO -CHECK® work?

THYRO-CHECK® uses a couple of antibodies detecting specifically TSH hormone by producing a coloured test line under the T mark of the cassette.

A control line capturing the reagent excess appears as a coloured line under the C mark of the cassette. In case both lines appear, the test indicates that the level of TSH is higher than normal ($<5\mu\text{IU/mL}$ determined against W.H.O.* reference).

*World Health Organisation

When should the test be performed?

In case of hypothyroidism symptoms such as feeling tired, depressed or cold regularly, weight gain, dry skin, brittle hair, enduring constipation or menstrual cycle irregularities in women, it is recommended to perform THYRO-CHECK®. THYRO-CHECK® can be used any time of the day.

Can the results be incorrect?

The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if THYRO-CHECK® gets wet before test performing or if the quantity of blood dispensed in the sample well is not correct. The plastic pipette provided in the box makes sure the collected blood volume is correct.

How to interpret the test if the colour and the intensity of the lines are different?

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete. The test should be considered as positive regardless the colour intensity of the test line (T), even weak.

What is the line that appears under the mark C (Control) for?

When this line appears, it only means that the test has been performed well.

If I read the result after 15 minutes, will the result be reliable?

No. The result should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

What do I have to do if the result is positive?

If the result is positive, it means that the TSH level in blood is higher than the norm ($5\mu\text{IU/mL}$) and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed.

What do I have to do if the result is negative?

If the result is negative, it means that the TSH level is below $5\mu\text{IU/mL}$ and is within the norm. However, if the symptoms persist, it is recommended to consult a doctor.

What is the accuracy of THYRO -CHECK®?

The THYRO-CHECK® is accurate and has been used for more than 10 years by professionals (hospitals, laboratories) in the field. Evaluation reports show an overall agreement higher than 98.1% [92.62 - 100**] with reference methods. Although this test is reliable, false positive or false negative results could be obtained.

**** CI 95%: 95% Confidence Interval.**

Information on hypothyroidism

<https://www.larousse.fr/encyclopedie/medical/thyroide/16584>

<https://www.endocrineweb.com/conditions/thyroid-nodules/thyroid-gland-controls-bodys-metabolism-how-it-works-symptoms-hyperthyroidism/>

<https://medlineplus.gov/lab-tests/tsh-thyroid-stimulating-hormone-test/>

Sterile lancet: **STERILE R** **CE** 1639

Owen Mumford Ltd
Brook Hill, Woodstock, Oxfordshire
OX20 1TU (UK)

EC REP GERMANY

Owen Mumford GmbH, Alte Häge 1,
63762 Großostheim, Germany

	Read the instructions before use	IVD	For in vitro diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiration date
	Manufacturer	EC REP	Authorized EU representative		

PHARMA SOUTHERN AFRICA
95 Aberdeen Street – Westdene, Johannesburg
2092, Republic of South Africa
(+27) 079 625 2452, www.pharmasa.co.za

VEDALAB
Rue de l'Expansion - ZAT du Londeau - Cerisé
BP 181 - 61006 ALENCON Cedex (France)
+33 2 33 27 56 25, www.vedalab.com

CE
0483

CHANGES DESCRIPTION

Changes type:

- N/A	Not Applicable (creation)
- Technical change	Addition, revision and/or removal of information related to the product.
- Administrative	Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	Creation

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

THYRO-CHECK®
Ref. 21084/ZA

2023/01
TSH-MCOT602301