

Self-testing device for under active thyroid detection in whole blood (TSH) (at-home test)

-  FAST
-  EASY
-  ACCURATE



Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

For more information, visit www.adventlife.net.

THYROID DISORDERS

Thyroid disorders are one of the most prevalent medical conditions in the world, especially in women, with an increasing proportion of the population suffering from an underactive thyroid gland (hypothyroidism).

WHAT IS HYPOTHYROIDISM?

Thyroid hormone production is regulated by the thyroid-stimulating hormone (TSH), which is produced by the pituitary gland. This in turn is regulated by the hypothalamus, an area of the brain. TSH ensures that enough thyroid hormones are produced to meet the body's needs. Hypothyroidism can occur if the thyroid gland's function is impaired or if it is not properly stimulated by the hypothalamus or pituitary gland. Therefore, an elevated TSH level indicates an underactive thyroid gland and this is the principle on which the Thyro-Check® is based to detect the condition of hypothyroidism.

WHAT ARE THE SYMPTOMS?

Symptoms of hypothyroidism include:

- Feeling tired and lethargic
- Weight gain
- Dry skin and brittle hair
- Forgetfulness and sometimes depression
- Feeling cold
- Constipation
- Menstrual disorders in women

SELF-TESTING DEVICE FOR DETECTION OF ALLERGY MARKER IN WHOLE BLOOD

PURPOSE

Thyroid disorders are one of the most prevalent medical conditions in the world, particularly for women, with an increasing rate of the population suffering from an underactive 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 the pituitary gland, 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 whole blood finger-prick sample.

FAST AND RELIABLE RESULTS

Time: 10-15 minutes.

Store between +4°C and +30°C. Do not freeze!

1 test per box.

Thyroid disorders are one of the most prevalent medical conditions in the world, particularly for women, with an increasing rate of the population suffering from an underactive 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 the pituitary gland, 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 whole blood finger-prick sample.

CLINICAL EVALUATION RESULTS

Sensitivity: 97.00 %

Specificity: 96.00 %

Accuracy: 97.00 %

PROVIDED MATERIALS:

- 1 sealed aluminium pouch containing:
 - 1 test device
 - 1 plastic pipette
 - 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.

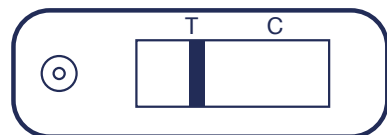
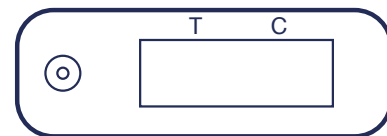
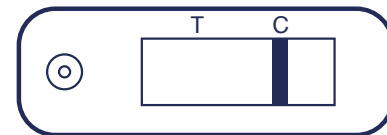
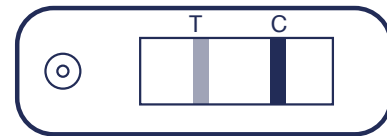
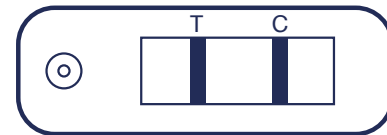
REQUIRED MATERIALS NOT PROVIDED:

Absorbent cotton and alcohol 70% vol. or alcohol pad.



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 hands with a clean towel.
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them within 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 $\frac{1}{4}$ of the way until you feel it separate from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished.
4. Clean the end of the middle finger or ring finger with cotton moistened with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. Press the platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button.
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.
8. Without pressing the blood drop that has formed, put the plastic pipette in contact with the blood sample. The blood migrates into the pipette through capillarity to the line indicated on the pipette. You may rub your finger again to obtain more blood if the line is not reached. Avoid air bubbles as much as possible.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb.
10. Wait 30-40 sec for the blood to be completely 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 of the device with an interval of 2-3 seconds between each drop.
11. Read the result after 10 minutes. Do not interpret after 15 minutes.



Positive: Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be weaker than the intensity of the line C. This result means that the TSH level in the blood is higher than the norm. You should consult a doctor as you may have a thyroid gland dysfunction.

Negative: Only one coloured line appears under the mark C (Control). This result means that the TSH level in the blood is normal and that your thyroid gland is functioning normally.

Invalid: No line appears or a coloured line appears under the mark T (Test) without any line under the mark C. 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 a new THYRO-Check® device and a new blood sample.

NOTE:

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

This test is exclusively intended for in vitro diagnostics use. External use only. **DO NOT SWALLOW.**

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.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.

Do not reuse the THYRO-Check® test.

Keep out of reach of children.

After use, all the components can be discarded in a dustbin.

Not suitable for children under 6 years old.