REF OTS-402H

CE 0123

my health checked™

myhealthchecked.com

Instructions for use

ENGLISH

TSH Rapid Test Cassette

Thyroid (TSH) Rapid Test

INTENDED USE

A rapid test for the qualitative detection of human thyroid stimulating hormone (TSH) in whole blood to help diagnose hypothyroidism (underactive thyroid).
For self-testing *in vitro* diagnostic use only.

SUMMARY

Thyroid stimulating hormone (also known as thyrotropin, thyrotropic hormone, TSH, or hTSH for human TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4), and then triiodothyronine (T3) which stimulates the metabolism of almost every tissue in the body.[1] It is a glycoprotein hormone synthesised and secreted by thyrotropic cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid.[2,3] TSH (with a half-life of about an hour) stimulates the thyroid gland to secrete the hormone thyroxine (T4), which has only a slight effect on metabolism. T4 is converted to triiodothyronine (T3), which is the active hormone that stimulates metabolism. About 80% of this conversion is in the liver and other organs, and 20% in the thyroid itself.[1] Testing of thyroid stimulating hormone (TSH) levels in the blood is considered the best initial test for hypothyroidism.[4] It is important to note the statement from the Subclinical Thyroid Disease Consensus Panel: "There is no single level of TSH at which clinical action is always either indicated or contraindicated. The higher the TSH, the more compelling is the rationale for treatment. It is important to consider the individual clinical context (e.g. pregnancy, lipid profile, ATPO antibodies)".[5] The Thyroid (TSH) Rapid Test qualitatively detects the presence of TSH in whole blood specimens at the sensitivity of 5 µlU/mL. The Thyroid (TSH) Rapid Test is a simple test that utilises a combination of monoclonal antibodies to selectively detect elevated levels of TSH in whole blood to aid diagnosis of hypothyroidism (underactive thyroid).

PRECAUTIONS

Please read all the information in this Instructions for use before performing the test
- For self-testing *in vitro* diagnostic use only
- Do not eat, drink or smoke in the area where the specimens or kits are handled
- Store in a dry place at 2-30°C (36-86°F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional
- Follow the indicated time strictly
- Use the test only once. Do not dismantle and touch the test window of the test cassette
- The kit must not be frozen or used after the expiration date printed on the package
- Keep out of the reach of children
- The used test should be discarded in your general household waste

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable up until the expiration date printed on the sealed pouch.
The test must remain in the sealed pouch until use. Do not freeze. Do not use after the expiration date.

MATERIALS PROVIDED

• Test cassette • Capillary dropper • Buffer • Alcohol pad • Lancet • Plaster • Product summary leaflet • Instructions for use

MATERIALS NOT PROVIDED

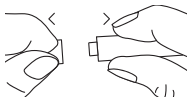
• Timer

PREPARATION

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it.
3. Open the pouch, remove the dropper, buffer vial, lancet, alcohol pad and test cassette placing them on a clean, level surface.
4. Perform the test within one hour with best results obtained if the test is performed immediately after opening the foil pouch.

INSTRUCTIONS

1



Carefully pull off and dispose of the cap on the lancet.

2

Use the alcohol pad to clean the fingertip which will be pricked with the lancet. Allow to air dry.

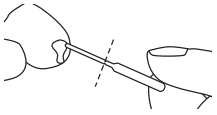
3

Press the orange end of the lancet down against the fingertip to prick the puncture site. The tip retracts automatically and safely after use.

4

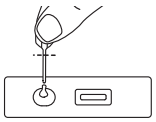
Without touching the puncture site, massage the hand towards the fingertip, keeping the hand pointing downwards to obtain the sample of blood.

5



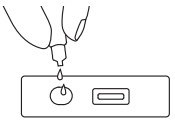
Without squeezing the capillary dropper bulb, place the end of the capillary tube in the blood until it reaches the fill line. Massage your finger again to obtain more blood if the blood does not reach the indicated line. Avoid air bubbles.

6



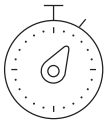
Transfer the collected blood into the sample well (S) of the cassette, by squeezing the dropper bulb. Apply the spot plaster to puncture site if required.

7



Unscrew the cap of the buffer vial and add 2 drops of buffer into the buffer well (B) of the cassette.

8



Start a timer and wait for the coloured line(s) to appear.

9

Read results at 10 minutes. Do not interpret the result after 20 minutes.

READING THE RESULTS

Positive 	**Positive** **Two coloured lines appear. Both T (test) and C (control) line appear.** This result means that the TSH level is higher than the normal (5 μIU/mL) and that you should consult a physician.
Negative 	**Negative** **One coloured line appears. Only control line appears (C).** This result means that the TSH level is not in the range to consider hypothyroidism.
Invalid 	**Invalid** **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

CONTROL PROCEDURE

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. The Thyroid (TSH) Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of TSH in whole blood specimens only. Neither the quantitative value nor the rate of increase in TSH concentration can be determined by this qualitative test.
2. The Thyroid (TSH) Rapid Test is only for screening primary hypothyroidism of adults, not for neonates.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A positive test must be confirmed using a quantitative laboratory TSH assay.
5. False positive results can occur due to heterophilic (unusual) antibodies. In certain clinical conditions such as central hypothyroidism, TSH levels may be normal/ low, despite hypothyroidism. Medical consultation is recommended to exclude such cases.
6. For central/secondary hypothyroidism, TSH is not a reliable biomarker, which occurs in 1 out of 1,000 hypothyroidism cases.

PERFORMANCE CHARACTERISTICS

Accuracy

A clinical evaluation was conducted comparing the results obtained using the TSH Test to ELISA. The in-house clinical trial included 220 whole blood specimens. The results demonstrated 98.2% specificity and 98.2% sensitivity with an overall accuracy of 98.2%.

Method		ELISA		Total Results
	Results	Positive	Negative	
Thyroid (TSH) Rapid Test	Positive	53	3	56
	Negative	1	163	164
	Total Results	54	166	220

Relative Sensitivity: 98.2% (95%CI*: 90.1%-99.9%)
Relatively Specificity: 98.2% (95%CI*: 94.8%-99.6%)
Accuracy: 98.2% (95%CI*: 95.4%-99.5%)

*Confidence Interval

FAQs

1. How does the Thyroid (TSH) Rapid Test work?
The thyroid stimulating hormone (TSH) activates thyroid gland. Therefore a TSH level over 5 μIU/mL in case of a positive result, indicates an under active thyroid (hypothyroidism), which needs more TSH.

2. When should the test be used?
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 occur, it is recommended to perform the Thyroid (TSH) Rapid Test for screening purposes. The Thyroid (TSH) Rapid Test can be used any time of the day. However, it cannot, and should not be performed in case of hormonal thyroid medical treatment.

3. Can the result be incorrect?
The results are accurate as long as the instructions are carefully followed. However, the result can be incorrect if the test cassette gets wet before performing the test or if the quantity of blood dispensed in the sample well is not sufficient, or if the number of buffer drops are less than 2 or more than 3. The capillary dropper provided in the box allows making sure the collected blood volume is correct. Due to immunological principles involved, there is the chance of a false result in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. 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 clearly visible. The test should be considered as positive whatever the colour intensity of the test line is.

5. If I read the result after 20 minutes, will the result be reliable?
No. The result should be read at 10 minutes after adding the buffer. The result is unreliable after 20 minutes.

6. 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 normal (5 μIU/mL) and that you should consult a physician to show the test result. Then, the physician will decide whether additional analysis should be performed.

7. 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 μIU/mL and is within the normal range. Although rare, hyperthyroidism cannot be excluded based on such test results. If the symptoms persist, it is recommended to consult a physician.

BIBLIOGRAPHY

1. Merck Manual of Diagnosis and Therapy, Thyroid gland disorders.
2. The American Heritage Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company. 2006. ISBN 0-395-82517-2.
3. Sacher R, Richard A. McPherson (2000). Widmann's Clinical Interpretation of Laboratory Tests, 11th ed. F.A. Davis Company. ISBN 0-8036-0270-7.
4. So, M; MacIsaac, RJ; Grossmann M (August 2012). "Hypothyroidism". Australian Family Physician 41 (8): 556–62.
5. Surkset. al.,JAMA 291:228, 2004. Daniel,GH, Martin, JB, Neuroendocrine Regulation and Diseases of the Anterior Pituitary and Hypothalamus in Wilson, JD, Braunwald, E., Isselbacher, KJ, et. al., Harrison's Principles of Internal Medicine, 12th Edition, McGraw-Hill, Inc., New York, NY, 1991, p. 1666)

INDEX OF SYMBOLS

	Manufacturer		Tests per kit	EC REP	Authorised Representative in EU
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		

Hangzhou AllTest Biotech Co.,Ltd. #550, Yinhai Street, Hangzhou Economic & Technological Development Area Hangzhou, 310018 P.R. China	CE 0123	EC REP	MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany
Lancet:			
Promisemed Hangzhou Meditech Co., Ltd. No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China	CE 0197	EC REP	MT Promedt Consulting GmbH, Altenhofstr. 80 66386 St., Ingbert, Germany
OR			
Ningbo Medsun Medical Co., Ltd. No. 55 Jinxi Road, Zhenhai 315221 Ningbo People's Republic of China	CE 0123	EC REP	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Alcohol pad:			
Jiangsu Sunclean Medical Co., Ltd. No.11 Fenghuang South Road, Hutang Town, Wujin District 213162 Changzhou City, Jiangsu Province, P.R. China	CE 0123	EC REP	Medpath GmbH, Mies-van-der-Rohe Strasse 8, 80807 Munich, Germany
OR			
Ningbo Medsun Medical Co., Ltd. No. 55 Jinxi Road, Zhenhai 315221 Ningbo People's Republic of China	CE	EC REP	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Plaster:			
Nantong City YOJO Medical Products C, Ltd Industrial Park, Sanxing Town, Haimen City, Jiangsu Province 226112 China	CE 0197	EC REP	SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Number: 14601325500
Revision date: 2023-02-03