

REF OTS-402H English

A rapid test for the qualitative detection of human Thyroid Stimulating Hormone (TSH) in human whole blood. For self-testing *in vitro* diagnostic use only.

【INTENDED USE】

The TSH Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of TSH in human whole blood at a cut-off concentration of 5 $\mu\text{U/mL}$. This assay provides a preliminary diagnostic test result and can be used to screening for TSH.

【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 synthesized and secreted by thyrotrope 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.

Testing of thyroid stimulating hormone 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 TSH Rapid Test Cassette (Whole Blood) is a rapid test that qualitatively detects the presence of TSH in whole blood specimen at the sensitivity of 5 $\mu\text{U/mL}$. The TSH Rapid Test Cassette (Whole Blood) is a simple test that utilizes a combination of monoclonal antibodies to selectively detect elevated levels of TSH in whole blood.

【PRINCIPLE】

The TSH Rapid Test Cassette (Whole Blood) is a qualitative membrane based immunoassay for the detection of Thyroid Stimulating Hormone (TSH) in whole blood. In this test procedure, anti-TSH antibody is immobilized in the test line region and coated particles. After specimen is added to the specimen well of the cassette, it reacts with anti-TSH antibody coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-TSH antibody. Positive specimens react with the specific anti-TSH antibody coated particles to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【PRECAUTIONS】

Please read all the information in this package insert 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 according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【MATERIALS PROVIDED】

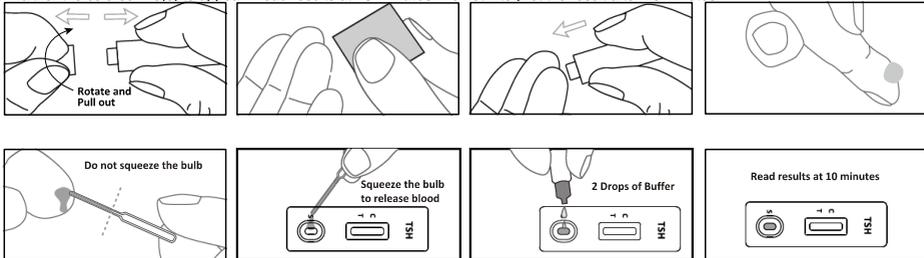
- Test cassette • Capillary dropper • Buffer • Alcohol pad • Lancet • Package insert • Brand Card

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer

【PROCEDURE】

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it. Open the foil pouch and get out the cassette.
3. Carefully pull off and dispose the released cap of the lancet.
4. Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site.
5. Press the lancet, on the side from where the cap was extracted; against the fingertip (Side of ring finger is advised). The tip retracts automatically and safely after use.
6. Keeping the hand down massage the end that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood migrates into the capillary dropper to the line indicated on the capillary dropper.
You may massage again your finger to obtain more blood if the line is not reached. Avoid air bubbles.
8. Put the blood collected into the sample well of the cassette, by squeezing on the dropper bulb.
9. Wait for the blood to be totally dispensed in the well. Unscrew the cap of the buffer bottle and add **2 drops of buffer** into the sample well of the cassette.
10. Wait for the colored line(s) to appear. Read results at **10 minutes**. Do not interpret the result after 20 minutes.



【READING THE RESULTS】



POSITIVE: Two colored lines appear. Both T (Test) and C (Control) line appear.
This result means that the TSH level is **higher than the normal (5 $\mu\text{U/mL}$)** and that you should consult a physician.



NEGATIVE: One colored line appears. Only control line (C) appears.
This result means that the TSH level is not in the range to consider Hypothyroidism.



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 TSH Rapid Test Cassette (Whole Blood) 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 TSH Rapid Test Cassette (Whole Blood) is only for screening the primary hypothyroidism of adult population, not for neonates.

- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- A positive test must be confirmed using a quantitative laboratory TSH assay.
- 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.
- 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	Results	ELISA		Total Results
		Positive	Negative	
TSH Rapid Test Cassette (Whole Blood)	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

【EXTRA INFORMATIONS】

1. How does the TSH test work?

The Thyroid Stimulating Hormone (TSH) activates thyroid gland. Therefore a TSH level over 5 $\mu\text{U/mL}$ 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 a TSH Rapid Test for screening purpose. The 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 far as the instructions are carefully respected. Nevertheless, the result can be incorrect if the TSH Rapid Test cassette gets wet before test performing 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. Besides, due to immunological principles involved, there exist the chances of false results 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 color and the intensity of the lines are different?

The color 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 color 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 $\mu\text{U/mL}$) 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 $\mu\text{U/mL}$ and is within the normal range. A case of Hyperthyroidism, though rare, but cannot be excluded based on such test results. However, if the symptoms persist, it is recommended to consult a physician.

【BIBLIOGRAPHY】

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- Sacher R, Richard A, McPherson (2000). Widmann's Clinical Interpretation of Laboratory Tests, 11th ed. F.A. Davis Company. ISBN 0-8036-0270-7.
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- 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

	Consult instructions for use
	For <i>in vitro</i> diagnostic use only
	Store between 2-30 °C
	Do not use if package is damaged

	Tests per kit
	Use by
	Lot number
	Manufacturer

	Authorized representative in EU
	Do not reuse
	Catalog #
	Caution

Hangzhou AllTest Biotech Co.,Ltd.
 #550, Yinhai Street
 Hangzhou Economic & Technological Development Area
 Hangzhou, 310018 P.R. China
 Web: www.alltests.com.cn Email: info@alltests.com.cn

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

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 MT Promed Consulting GmbH
 Altenhofstr. 80 66386 St. Ingbert, Germany

or
Ningbo Medsun Medical Co.,Ltd.
 No. 55 Jinxi Road, Zhenhai 315221 Ningbo
 P.R., China

CE 0123

EC REP
 Shanghai International Holding Corp. GmbH (Europe)
 Eiffestrasse 80 20537 Hamburg, Germany

Alcohol Pad
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