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PARAMCARE™

TSH Rapid Test Kit (Serum/Plasma/Whole blood)

The TSH Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of TSH in human serum/plasma/whole blood specimens.
For professional / self and in-vitro diagnostic use only.

ORDER INFORMATION

Pack Size	REF
01 Test	PTSH 01
05 Tests	PTSH 05
10 Tests	PTSH 10
25 Tests	PTSH 25
50 Tests	PTSH 50

CLINICAL SIGNIFICANCE

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. [1] Laboratory testing of thyroid stimulating hormone* levels in the blood is considered the best initial test for hypothyroidism. [4] *TSH It is important to note the statement from the Subclinical Thyroid Disease Consensus Panel: "There is no single level of serum 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/Serum/Plasma) is a rapid test that qualitatively detects the presence of TSH in whole Blood, serum or plasma specimen at the sensitivity of 5µlU/ml. The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of monoclonal antibodies to selectively detect elevated levels of TSH in whole blood, serum or plasma

PRINCIPLE

The Paramcare TSH RAPID TEST The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of Thyroid Stimulating Hormone (TSH) in whole blood, serum, or plasma. In this test procedure, anti-TSH antibody is immobilized in the test line region and coated particles respectively. After specimen is added to the specimen well of the device, 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

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert • Alcohol Swab
• Lancet (for fingerstick whole blood only)

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only) • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by venipuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

To collect Fingerstick Whole Blood specimens:

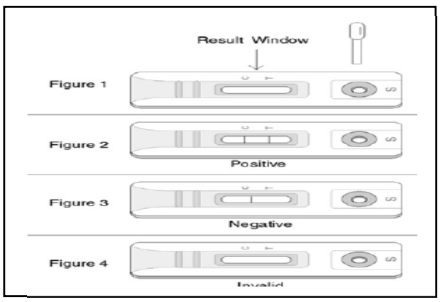
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the sample well of the test cassette by using a sample dropper. Avoid air bubbles.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Hold the dropper vertically and transfer 1 drop (25 µL) drops of serum or plasma and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer. See illustration below.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drop (25 µL) drops of whole blood and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer. See illustration below.
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL (1 drops) of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



1) Positive
The control line (C) and test line (T) lines are visible on the test device. This is positive for TSH hormone. This is indicative of presence of TSH.
2) Negative
The control line is the only visible line on the test device. No TSH hormone were detected
3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control
Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test
1. The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of TSH in whole blood, serum or plasma 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/Serum/Plasma) is only for screening the primary hypothyroidism of adult population, 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.
6. For Central/ Secondary Hypothyroidism, TSH is not a reliable biomarker, which occurs in 1 out of 1,000 Hypothyroidism cases

Detection Limitation
The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect TSH hormone as low as 5 mIU/L.

Sensitivity and Specificity
A total of 305 specimens were collected from susceptible subjects and tested by TSH Rapid Test and a commercial TSH Rapid test as reference. Comparison for all subjects is showed in the following table.

Method		Other Rapid Test		Total Test
TSH Rapid Card Test	Result	Positive	Negative	
	Positive	75	0	**75**
	Negative	0	230	**230**
Total Results		**75**	**230**	**305**

Sensitivity: >98% (95% CI*: 94.4%-99.8%) *Confidence Interval Specificity: >98% (95%CI*: 96.7%-99.6%)

Cross-reactivity
The TSH Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested for sTnI (Skeletal muscle TnI-10µg/mL), cardiac mysosin (20 µg/mL), HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances
The following compounds have also been tested using the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/d.l

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GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.
Email: contact@paramcarelifesciences.com
Website: www.paramcarelifesciences.com