todylaboratories®

Rapid Tests

CE IVD REF C61RT1001

TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of human Thyroid Stimulating Hormone (TSH) in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The TSH Rapid Test Cassette (Whole Blood/ Serum/ Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Thyroid Stimulating Hormone (TSH) in whole blood, serum, or plasma to aid in the screening the adult population for primary hypothyroidism by medical professionals. It is not indicated for use in screening neonates for hypothyroidism.

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. [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 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. 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.

REAGENTS

The test contains anti-TSH antibody coated particles and anti-TSH antibody immobilized on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

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.

SPECIMEN COLLECTION AND PREPARATION

- The TSH Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- 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 test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 50μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

• Test Cassettes • Droppers • Buffer • Package Insert

Materials required but not provided

• Specimen Collection Containers • Centrifuge • Timer • Lancets (for fingerstick whole blood only) • Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma specimen**:

• Hold the dropper vertically and transfer **1 drop of serum or plasma (approximately 25μL)** to the specimen well then **add 1 drop of buffer (approximately 40 μL)**, and start the timer. See illustration below.

For **Venipuncture Whole Blood specimen**:

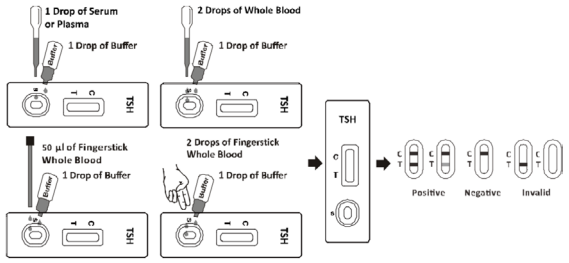
• Hold the dropper vertically and transfer **2 drops of whole blood (approximately 50μL)** to the specimen well, then **add 1 drop of buffer (approximately 40 μL)**, and start the timer. See illustration below.

For **Fingerstick Whole Blood specimen**:

• To use a capillary tube: Fill the capillary tube and **transfer approximately 50 μL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 1 drop of buffer (approximately 40 μL)** and start the timer. See illustration below.

• To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen (approximately 50μL)** to fall into the specimen area of test cassette, then **add 1 drop of buffer (approximately 40 μL)** and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).A positive result means that the TSH level is above the cut-off level of 5μlU/ml.

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of TSH present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).A negative result means that the TSH level is below the cut-off level of 5μlU/ml.

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

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. 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

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.

EXPECTED VALUES

The reference range for serum TSH concentration in normal subjects varied based upon the subject's age and the assay methods used. TSH values in normal subjects average 0.5 to 5.0μlU/ml.[6] An elevated TSH level is a sensitive indicator of the underproduction of T4 by the thyroid gland that is primary hypothyroidism. Suspect primary hypothyroidism when TSH >5μlU/ml. So the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) has a sensitivity of 5μlU/ml.

PERFORMANCE CHARACTERISTICS

Accuracy

The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with elevated TSH and normal TSH specimens. A commercially available TSH ELISA kit served as the reference method for the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma). The specimen was considered positive if the result of ELISA was> 5μlU/ml. The specimen was considered negative if the result of ELISA was <5μlU/ml. The result shows that the sensitivity of the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.1% and the specificity is 98.2% relative to ELISA.

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

Relative Sensitivity: 98.1% (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 Intervals

Sensitivity and Cross-Reactivity

The TSH Rapid Test Cassette detects TSH at a concentration of 5 μlU/ml. The addition of LH (500 mIU/ml), FSH (2,000 mIU/ml), and 200,000 mIU/ml hCG to negative (0 μlU/ml TSH) and positive (5μlU/ml TSH) specimens showed no cross-reactivity.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: 0 μlU/ml TSH, 5 μlU/ml TSH, 10 μlU/ml TSH, 50 μlU/ml TSH. The negative and positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: 0 μlU/ml TSH, 5 μlU/ml TSH, 10 μlU/ml TSH, 50 μlU/ml TSH. Three different lots of the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested. The specimens were correctly identified >99% of the time.

Interfering Substances

The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for the following potentially interfering substances, spiked with TSH negative and positive specimens.

Acetaminophen	20 mg/dl	Caffeine	20 mg/dl
Acetylsalicylic Acid	20 mg/dl	Gentisic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl	Glucose	2 mg/dl
Atropine	20 mg/dl	Hemoglobin	20 mg/dl
Triglycerides	1,200 mg/dl	Bilirubin	40 mg/dl
Aspirin	20 mg/dl	Albumin	2000 mg/dl

None of the substances at the concentration tested interfered in the assay.

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