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

Package Insert

A rapid test 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 intended for use in screening neonates for hypothyroidism.

**SUMMARY**

Thyroid-stimulating hormone (also known as thyrotropin, thyroid-stimulating hormone, or TSH, for human TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4), and then to triiodothyronine (T3), which are the main thyroid hormones. It is the most potent of the three major plasma hormones that regulate thyroid metabolism. About 80% of this conversion is in the liver and other organs, and 20% in the thyroid itself.

Laboratory testing of thyroid stimulating hormone* levels in the blood is considered the best initial test for hypothyroidism. TSH

It is important to note the statement from the Subclinical Thyroid Disease Consensus Panel: "There is no 'normal range' of serum TSH at which clinical action is always either indicated or contraindicated. The TSH concentration is the primary diagnostic test used to identify hypothyroidism. However, no single level of serum TSH at which clinical action is always either indicated or contraindicated. The

**SPECIMEN COLLECTION AND PREPARATION**

**PRECAUTIONS**

- Do not use if package is damaged.
- Store between 2-20°C. Do not use beyond the expiration date.

**REAGENTS**

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

**PREPARATION**

- Wash the test cassette to ensure that the test area is clean before use.

**INTERPRETATION OF RESULTS**

1. **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 5μU/L. **NOTE**: The intensity of the color in the test region (T) will depend on the concentration of TSH in the specimen. Higher color intensity indicates a higher TSH level. The level of TSH in the test region (T) should be considered positive.

2. **Negative**: No colored line appears in the control region (C). A negative result means that the TSH level is below the cut-off level of 5μU/L. **NOTE**: The intensity of the color in the test region (T) will depend on the concentration of TSH in the specimen. Higher color intensity indicates a higher TSH level. The level of TSH in the test region (T) should be considered negative.

**QUALITY CONTROL**

- A positive control is included in the test. A colored line appearing in the positive control area (P) indicates that the test has worked properly. If no line appears in the positive control area (P), the test should be repeated with a new test cassette.

**LIMITATIONS**

1. The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test is not intended for use on pregnant women, neonates, or individuals with known hypersensitivity to the test reagents.

2. As with all diagnostic tests, results must be interpreted with other clinical information available to the physician.

3. A positive test must be confirmed using a quantitative laboratory TSH assay.

4. Elevated TSH levels are seen in both hypothyroidism and hyperthyroidism. In certain clinical conditions such as central hypothyroidism, TSH levels may be normal/low, despite hypothyroidism. Secondary hypothyroidism, TSH is not a reliable biomarker, which occurs in 1 out of 1,000 hypothyroidism cases.

**EXPECTED VALUES**

Recommendation range for serum TSH concentration in normal subjects varies based upon the subject’s age and the assay methods used. TSH values in normal subjects average 0.5 to 5.0 μU/mL. 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 >5.0 μU/mL. So the TSH Rapid Test Cassette is capable of detecting hypothyroidism.

**REFERENCE**

- The TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with elevated TSH and hypothyroidism patients. The TSH ELISA kit was used as the reference for the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma). The specimen was considered positive if the result of ELISA was >10 μU/mL. The specimen was considered negative if the result of ELISA was <5 μU/mL. The result shows that the sensitivity of the TSH Rapid Test Cassette (Whole Blood/Serum/Plasma) is 95.9% and the specificity is 80.0%.

**Performance Characteristics**

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**Sensitivity and Cross-Reactivity**

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

**Suppliers**

- Acetaminophen: 20 mg/ml
- Ascorbic Acid: 20 mg/ml
- Caffeine: 20 mg/ml
- Glucose: 2 mg/ml
- Metabolism: 20 mg/ml
- Triglycerides: 50 mg/ml
- Aspirin: 200 mg/ml

**Additional Information**

- 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.
- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
- For professional in vitro diagnostic use only. Do not use after the expiration date.