MAYO CLINIC LABORATORIES

# Test Definition: STSH

Thyroid-Stimulating Hormone-Sensitive (s-TSH), Serum

## Overview

### Useful For

Screening for thyroid dysfunction and detecting mild (subclinical), as well as overt, primary hypo- or hyperthyroidism in ambulatory patients

Monitoring patients on thyroid replacement therapy

Confirmation of thyrotropin (TSH, formerly thyroid-stimulating hormone) suppression in thyroid cancer patients on thyroxine suppression therapy

Prediction of thyrotropin-releasing hormone-stimulated TSH response

### Testing Algorithm

See Thyroid Function Ordering Algorithm in Special Instructions.

### Special Instructions

- Thyroid Function Ordering Algorithm

### Method Name

Electrochemiluminescent Immunoassay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

This is a standalone test for sensitive thyrotropin (s-TSH; formerly thyroid-stimulating hormone).

If a cascade approach is preferred, order THSCM / Thyroid Function Cascade, Serum, which utilizes a cascaded testing procedure to efficiently evaluate and monitor functional thyroid status. Serum s-TSH is the first-line test and when the s-TSH result is abnormal, appropriate follow-up tests will automatically be performed.

### Specimen Required

**Collection Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 0.6 mL
**Collection Instructions:**
1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged, and the serum aliquoted into a plastic vial within 2 hours of collection.

### Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Kidney Transplant Test Request
-Renal Diagnostics Test Request (T830)

### Specimen Minimum Volume

0.5 mL

### Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | OK |
| Gross icterus | OK |

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Serum | Refrigerated (preferred) | 7 days | |
| | Ambient | 7 days | |
| | Frozen | 30 days | |

## Clinical & Interpretive

### Clinical Information

Thyrotropin (TSH, formerly thyroid-stimulating hormone) is a glycoprotein hormone consisting of 2 subunits. The alpha subunit is similar to those of follicle-stimulating hormone, human chorionic gonadotropin, and luteinizing hormone. The beta subunit is different from those of the other glycoprotein hormones and confers its biochemical specificity.

TSH is synthesized and secreted by the anterior pituitary in response to a negative feedback mechanism involving concentrations of free triiodothyronine and free thyroxine. Additionally, the hypothalamic tripeptide, thyrotropin-releasing hormone, directly stimulates TSH production.

TSH interacts with specific cell receptors on the thyroid cell surface and gives rise to 2 main actions. First, it stimulates cell reproduction and hypertrophy. Second, it stimulates the thyroid gland to synthesize and secrete triiodothyronine and thyroxine.

Serum TSH concentrations exhibit a diurnal variation with the peak occurring during the night and the nadir occurring between 10 a.m. and 4 p.m. This biological variation does not influence the interpretation of the test result since most clinical TSH measurements are performed on ambulatory patients between 8 a.m. and 6 p.m.

When hypothalamic-pituitary function is normal, a log/linear inverse relationship between serum TSH and free thyroxine exists.

See Thyroid Function Ordering Algorithm in Special Instructions.

## Reference Values

0-5 days: 0.7-15.2 mIU/L
6 days-2 months: 0.7-11.0 mIU/L
3-11 months: 0.7-8.4 mIU/L
1-5 years: 0.7-6.0 mIU/L
6-10 years: 0.6-4.8 mIU/L
11-19 years: 0.5-4.3 mIU/L
> or =20 years: 0.3-4.2 mIU/L

For SI unit Reference Values, see https://www.mayocliniclabs.com/order-tests/si-unit-conversion.html

## Interpretation

In primary hypothyroidism, thyrotropin (TSH, formerly thyroid-stimulating hormone) levels will be elevated. In primary hyperthyroidism, TSH levels will be low.

The ability to quantitate circulating levels of TSH is important in evaluating thyroid function. It is especially useful in the differential diagnosis of primary (thyroid) from secondary (pituitary) and tertiary (hypothalamus) hypothyroidism. In primary hypothyroidism, TSH levels are significantly elevated, while in secondary and tertiary hypothyroidism, TSH levels are low or normal.

Elevated or low TSH in the context of normal free thyroxine is often referred to as subclinical hypo- or hyperthyroidism, respectively.

Thyrotropin-releasing hormone (TRH) stimulation differentiates all types of hypothyroidism by observing the change in patient TSH levels in response to TRH. Typically, the TSH response to TRH stimulation is exaggerated in cases of primary hypothyroidism, absent in secondary hypothyroidism, and delayed in tertiary hypothyroidism. Most individuals with primary hyperthyroidism have TSH suppression and do not respond to TRH stimulation with an increase in TSH over their basal value.

Sick, hospitalized patients may have falsely low or transiently elevated TSH.

## Cautions

Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Concentrations up to 1200 ng/mL may be present in specimens collected from patients taking extremely high doses of biotin up to 300 mg per day.(1) In a study among 54 healthy volunteers, supplementation with 20 mg/day biotin resulted in a maximum serum biotin

concentration of 355 ng/mL 1 hour post-dose.(2)

For assays employing antibodies, the possibility exists for interference by human anti-animal antibodies (ie, heterophile antibodies) in the patient specimen. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies (eg, human antimouse antibodies) that interfere with immunoassays. This may falsely elevate or falsely decrease the results.

Interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin, or ruthenium can occur.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings.

### Clinical Reference

1. Saint Paul LP, Debruyne D, Bernard D, Mock DM, Defer GL: Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis. Expert Opin Drug Metab Toxicol. 2016;12(3):327-344. doi: 10.1517/17425255.2016.1136288.
2. Grimsey P, Frey N, Bendig G, et al: Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. J Pharmacokinet Pharmacodyn. 2017;2(4),247-256
3. Fatourechi V, Lankarani M, Schryver P, Vanness D, Hall-Long K, Klee G: Factors influencing clinical decisions to initiate thyroxine therapy for patients with mildly increased serum thyrotropin (5.1-10.0 mIU/L). Mayo Clin Proc. 2003 May;78(5):554-560
4. Wilson JD, Foster DW, Kronenburg HM, Larsen PR: Williams Textbook of Endocrinology. 9th ed. Saunders Company; 1998
5. Melmed S, Polonsky KS, Larsen PR, Kronenberg H: Williams Textbook of Endocrinology. 12th ed. Saunders Company; 2011:348-414
6. Heil W, Ehrhardt V: Reference intervals for adults and children. 9th ed. Roche Diagnostics; 2009 Jul;V9.1
7. Freedman DB, Halsall D, Marshall WJ, Ellervik C: Thyroid disorders. In: Rifai N, Horvath AR, Wittwer CT: eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 6th ed. Elsevier; 2018:1572-1616

## Performance

### Method Description

The cobas e immunoassay thyrotropin (TSH, formerly thyroid-stimulating hormone) method employs monoclonal antibodies specifically directed against human TSH. A biotinylated monoclonal TSH-specific antibody and a monoclonal TSH-specific antibody labeled with a ruthenium complex react to form a sandwich complex. After the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier.(Package insert: Elecsys TSH. Roche Diagnostics; 12/2018)

# Test Definition: STSH

Thyroid-Stimulating Hormone-Sensitive (s-TSH), Serum

### PDF Report
No

### Day(s) Performed
Monday through Sunday

### Report Available
Same day/1 to 2 days

### Specimen Retention Time
7 days

### Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

## Fees & Codes

### Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

### Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

### CPT Code Information
84443

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| STSH | TSH, Sensitive, S | 11579-0 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| STSH | TSH, Sensitive, S | 11579-0 |