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 thyroid-stimulating hormone (TSH) 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

Advisory Information
This is a standalone test for sensitive 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 TSH is the first-line test and when the s-TSH result is abnormal, appropriate follow-up tests will automatically be performed.

Specimen Required

Patient Preparation: For 12 hours before this test do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Container/Tube:
- Preferred: Serum gel
- Acceptable: Red top

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 aliquoted within 2 hours of collection.

Specimen Minimum Volume

0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Mild OK; Gross reject</th>
<th>Mild OK; Gross OK</th>
<th>Mild OK; Gross OK</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Icterus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>7 days</td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information

Thyroid-stimulating hormone (TSH, thyrotropin) 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.
**Test Definition: STSH**

**TSH, Sensitive, S**

**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](https://www.mayocliniclabs.com/order-tests/si-unit-conversion.html)

**Interpretation**

In primary hypothyroidism, thyroid-stimulating hormone (TSH) 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**

For assays employing antibodies, the possibility exists for interference by human antianimal 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

Performance

Method Description
The Cobas e immunoassay thyroid-stimulating hormone (TSH) 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: Thyrotropin TSH, Roche Diagnostics Corporation, Indianapolis IN)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Sunday; Continuously

Analytic Time
Same day/1 day

Maximum Laboratory Time
2 days

Specimen Retention Time
7 days

Performing Laboratory Location
Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.
Test Definition: STSH
TSH, Sensitive, S

Test Classification
This test has been cleared or approved by the U.S. 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

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>STSH</td>
<td>TSH, Sensitive, S</td>
<td>11579-0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>STSH</td>
<td>TSH, Sensitive, S</td>
<td>11579-0</td>
</tr>
</tbody>
</table>