MAYO CLINIC LABORATORIES

Test Definition: THCSM

Thyroid Function Cascade, Monitor (without Thyroid Peroxidase Antibody), Serum

Overview

Useful For

Monitoring patients diagnosed with thyroid disease

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
FRT4C	T4 (Thyroxine), Free, S	Yes	No
T3C	T3 (Triiodothyronine), Total, S	Yes	No

Testing Algorithm

If thyrotropin (TSH) is less than 0.3 mIU/L, then free T4 (FT4, thyroxine) will be performed at an additional charge.

If free T4 is normal and the TSH is less than 0.1 mIU/L, then T3 (triiodothyronine) will be performed at an additional charge.

If TSH is greater than 4.2 mIU/L, then free T4 will be performed at an additional charge.

Method Name

Electrochemiluminescent Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 mL Serum
Collection Instructions: Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

Serum: 1 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	72 hours	
	Frozen	30 days	

Clinical & Interpretive

Clinical Information

This test utilizes a cascade testing approach to efficiently evaluate and monitor functional thyroid status.

The cascade begins with thyrotropin (TSH) as a screening assay. In patients with an intact pituitary-thyroid axis, TSH provides a physiologic indicator of the functional level of thyroid hormone activity. Increased TSH indicates inadequate thyroid hormone, and suppressed TSH indicates excess thyroid hormone.

Transient TSH abnormalities may be found in seriously ill, hospitalized patients, so this is not the ideal setting to assess thyroid function. However, even in these patients, TSH works better than total thyroxine (an alternative screening test).

When TSH is normal, no additional testing will be necessary. However, when the TSH result is abnormal, appropriate follow-up tests will automatically be performed.

If TSH is below 0.3 mIU/L or above 4.2 mIU/L, free T4 (thyroxine) is performed. The supplemental measurement of free T4 in patients with abnormal TSH measurements allows one to better assess the severity of the changes.

Serum T3 (triiodothyronine) levels often are depressed in patients who are sick and hospitalized, caused in part by the biochemical shift to the production of reverse T3. Therefore, T3 generally is not a reliable predictor of hypothyroidism. However, in a small subset of patients with hyperthyroidism, hyperthyroidism may be caused by overproduction of T3 (T3 toxicosis). To help diagnose and monitor this subgroup, T3 is measured on all specimens with suppressed TSH and normal free T4 concentrations.

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

Interpretation

In primary hypothyroidism, thyrotropin (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 test with an increase in TSH over their basal value.

Patients who are sick and hospitalized may have falsely-low or transiently-elevated TSH levels.

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/d.(1) In a study among 54 healthy volunteers, supplementation with 20 mg/d biotin resulted in a maximum serum biotin concentration of 355 ng/mL 1-hour postdose.(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 [HAMA]) 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.(3)

Clinical Reference

1. Peyro Saint Paul L, 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. TSH Reagent. Package insert. Roche Diagnostics; V2, 03/2020
4. Fatourechi V, Lankarani M, Schryver PG, Vanness DJ, Long KH, Klee GG. 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;78(5):554-560. doi:10.4065/78.5.554
5. Wilson JD, Foster D, Kronenburg HM, et al. Williams Textbook of Endocrinology. 9th ed. WB Saunders Company; 1998
6. Melmed S, Polonsky KS, Larsen PR, et al. Williams Textbook of Endocrinology. 12th ed. Elsevier Saunders Company; 2011:348-414
7. Heil W, Ehrhardt V. Reference Intervals for Adults and Children 2008. 9th ed. Roche Diagnostics; 09/2009

Performance

Method Description
The cobas e immunoassay thyrotropin (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: Elecsys TSH. Roche Diagnostics; V4.0, 02/2023)

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
84439-(if appropriate)
84480-(if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
THCSM	Thyroid Cascade (Monitor), S	11579-0

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