

Overview

Useful For

Assessing thyroid function when thyroid function disorders are suspected

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
T4F	T4 (Thyroxine), Free, S	No	Yes
T4CC	T4 (Thyroxine), Total Only, S	No	Yes

Method Name

Electrochemiluminescence Immunoassay

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 mL

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.625 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Ambient	72 hours	
	Refrigerated (preferred)	7 days	
	Frozen	30 days	

Clinical & Interpretive

Clinical Information

Total Thyroxine:

Thyroxine (T4) is synthesized in the thyroid gland. T4 is metabolized to triiodothyronine (T3) peripherally by deiodination. T4 is considered a reservoir or prohormone for T3, the biologically most active thyroid hormone. About 0.05% of circulating T4 is in the free, ie, unbound, portion. The remainder is bound to thyroxine-binding globulin), prealbumin, and albumin.

The hypothalamus secretes thyrotropin-releasing hormone, which stimulates the pituitary to release thyrotropin, formerly thyroid-stimulating hormone (TSH). TSH stimulates the thyroid to secrete T4. T4 is partially converted peripherally to T3. High amounts of T4 and T3 (mostly from peripheral conversion of T4) cause hyperthyroidism.

T4 and T3 cause positive feedback to the pituitary and hypothalamus with resultant suppression or stimulation of the thyroid gland as follows: decrease of TSH if T3 or T4 is high (hyperthyroidism) and increase of TSH if T3 or T4 is low (hypothyroidism).

Measurement of total T4 gives a reliable reflection of clinical thyroid status in the absence of protein binding abnormalities. However, changes in binding proteins can occur that affect the level of total T4 but leave the level of unbound hormone unchanged.

Free Thyroxine:

Free thyroxine comprises a small fraction of total thyroxine. The free T4 (FT4) is available to the tissues and is, therefore, the metabolically active fraction.

Elevations in FT4 cause hyperthyroidism, while decreases cause hypothyroidism.

Reference Values

T4 (THYROXINE), TOTAL ONLY

0-5 days: 5.0-18.5 mcg/dL

6 days-2 months: 5.4-17.0 mcg/dL

3 -11 months: 5.7-16.0 mcg/dL

1 -5 years: 6.0-14.7 mcg/dL

6 -10 years: 6.0-13.8 mcg/dL

11 -19 years: 5.9-13.2 mcg/dL

> or =20 years: 4.5-11.7 mcg/dL

T4 (THYROXINE), FREE

0-5 days: 0.9-2.5 ng/dL

6 days-2 months: 0.9-2.2 ng/dL

3-11 months: 0.9-2.0 ng/dL

1-5 years: 1.0-1.8 ng/dL

6-10 years: 1.0-1.7 ng/dL

11-19 years: 1.0-1.6 ng/dL

> or =20 years: 0.9-1.7 ng/dL

Cautions

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium also rarely occur and may interfere with this assay. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

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)

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
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 Sept;2(4):247-256. doi: 10.4155/ipk-2017-0013
3. Melmed S, Polonsky KS, Larsen PR, et al: *Williams Textbook of Endocrinology*. 12th ed. Elsevier Saunders; 2011:348-414

Performance**Method Description**

Total Thyroxine:

Testing is performed on a Roche cobas instrument. The Roche thyroxine (T4) assay is a competitive assay using electrochemiluminescence detection. Bound T4 is released from binding proteins by 8-anilino-1-naphthalene sulfonic acid. Patient specimen is incubated with sheep polyclonal anti-T4 antibody labeled with ruthenium. Streptavidin-coated microparticles and biotinylated T4 are added for a second incubation during which the still free binding sites of the labeled antibody become occupied. The resulting immunocomplex becomes bound to the solid phase by 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. Unbound substances are then removed, and application of a voltage to the electrode induces the electrochemiluminescent emission. This signal is measured against a calibration

curve to determine patient results.(Package insert: Elecsys T4. Roche Diagnostics; V2 English, 10/2022)

Free Thyroxine:

Testing is performed on a Roche cobas immunoassay analyzer. In the Roche free T4 assay, the determination of free T4 is made with the aid of a specific anti-T4 antibody labeled with a ruthenium complex. After addition of biotinylated T4 and streptavidin-coated microparticles, the still free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire 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. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier.(Package insert: Elecsys FT4II. Roche Diagnostics; V1, 01/2019)

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

Rochester

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

84436

84439

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
T4FT4	T4 (Thyroxine), Total and Free	90224-7

Result ID	Test Result Name	Result LOINC® Value
T4F	T4 (Thyroxine), Free, S	83122-2
T4CC	T4 (Thyroxine), Total Only, S	83119-8