

## Overview

### Useful For

Monitoring treatment with synthetic hormones (synthetic triiodothyronine [T3] will cause a low total thyroxine [T4])

Monitoring treatment of hyperthyroidism with thiouracil and other anti-thyroid drugs

Index of thyroid function when the thyroxine-binding globulin is normal and non-thyroidal illness is not present

### Testing Algorithm

For information see [Thyroid Function Ordering Algorithm](#).

### Special Instructions

- [Thyroid Function Ordering Algorithm](#)

### Method Name

Electrochemiluminescence Immunoassay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

This test cannot be used in patients receiving treatment with lipid-lowering agents containing dextrothyroxine unless therapy is discontinued for 4 to 6 weeks to allow the physiological state to become reestablished prior to testing.

### 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

0.75 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	
	Frozen	30 days	

### Clinical & Interpretive

#### Clinical Information

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 and non-thyroidal illness. However, changes in binding proteins can occur that affect the level of total T4 but leave the level of unbound hormone unchanged.

#### Reference Values

##### Pediatric

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

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

For SI unit Reference Values, see [www.mayocliniclabs.com/order-tests/si-unit-conversion.html](http://www.mayocliniclabs.com/order-tests/si-unit-conversion.html)

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**Interpretation**

Values of more than 11.7 mcg/dL in adults or more than the age-related cutoffs in children are seen in hyperthyroidism and in patients with acute thyroiditis.

Values below 4.5 mcg/dL in adults or below the age-related cutoffs in children are seen in hypothyroidism, myxedema, cretinism, chronic thyroiditis, and occasionally, subacute thyroiditis.

Increased total thyroxine (T4) is seen in pregnancy and patients who are on estrogen medication. These patients have increased total T4 levels due to increased thyroxine-binding globulin (TBG) levels.

Decreased total T4 is seen in patients on treatment with anabolic steroids or nephrosis (decreased TBG levels).

A thyrotropin-releasing hormone stimulation test may be required for certain cases of hyperthyroidism.

Clinical findings are necessary to determine if thyrotropin, TBG, or free T4 testing is needed.

**Cautions**

In pregnancy, incomplete release of thyroxine (T4) from its binding proteins might result in falsely low total T4 levels. Therefore, total T4 should not be used as the only marker for thyroid function evaluation.

Thyrotropin (TSH) may be better than T4 as the initial test of thyroid status. TSH is elevated in primary hypothyroidism. TSH is low in primary hyperthyroidism.

Free T4 may more accurately measure the physiologic amount of T4.

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.

Autoantibodies to thyroid hormones can interfere with testing.

Binding protein anomalies may cause values that deviate from the expected results. Pathological concentrations of binding proteins can lead to results outside the reference range, although the patient may be in a euthyroid state.

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.<sup>(1)</sup> 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.<sup>(2)</sup>

**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. Ross DS, Burch HB, Cooper DS, et al: 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid*. 2016 Oct 26(10):1343-14214
4. Persani L, Cangiano B, Bonomi M: The diagnosis and management of central hypothyroidism in 2018. *Endocr Connect*. 2019 Feb;8(2):R44–R54 doi:10.1530/EC-18-0515

## Performance

### Method Description

The Roche Elecsys T4 (thyroxine) 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; V 2.0 English, 03/2020)

### PDF Report

No

### Day(s) Performed

Monday through Friday

### Report Available

1 to 3 days

### Specimen Retention Time

3 months

### 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

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
T4	T4 (Thyroxine), Total Only, S	83119-8

Result ID	Test Result Name	Result LOINC® Value
T4	T4 (Thyroxine), Total Only, S	83119-8