

## Overview

### Useful For

Cases in which total thyroid hormone levels do not correlate with thyrometabolic status, most commonly with pregnancy or the use of contraceptive steroids

### Method Name

Solid-Phase Chemiluminescent Assay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Patient Preparation:** For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).

**Supplies:** Sarstedt Aliquot Tube 5 mL (T914)

#### Collection Container/Tube:

**Preferred:** Red top

**Acceptable:** Serum gel

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.5 mL serum

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

### Specimen Minimum Volume

Serum: 0.35 mL

### Reject Due To

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

### Specimen Stability Information

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

|  |        |         |  |
|--|--------|---------|--|
|  | Frozen | 30 days |  |
|--|--------|---------|--|

## Clinical & Interpretive

### Clinical Information

Thyroxine binding globulin (TBG) is the high-affinity serum binding protein for thyroxine and triiodothyronine. Normally, the thyroid adjusts to changing concentrations of TBG by producing more, or less, thyroid hormone to maintain a constant level of metabolically important free hormone.

Elevated TBG levels are associated with influences such as pregnancy, genetic predisposition, oral contraceptives, and estrogen therapy. TBG levels can decrease with androgenic or anabolic steroids, large doses of glucocorticoids, hypoproteinemic states, liver disease, nephrotic syndrome, and congenital TBG variants.

### Reference Values

Males: 12-26 mcg/mL

Females: 11-27 mcg/mL

For International System of Units (SI) conversion for Reference Values, see

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

### Interpretation

A change in thyroxine-binding globulin (TBG) concentration may be of hereditary, pathophysiologic, or pharmacologic origin.

The TBG concentration indicates whether an abnormally high or low total thyroid hormone concentration is offset by a parallel increase or decrease in TBG concentration.

In TBG deficiency, one may find euthyroid patients with extremely low total thyroxine (T4) values. Conversely, patients with high TBG levels may be clinically euthyroid with high serum total T4 values.

Twenty-four specimens obtained during various stages of pregnancy yielded results ranging from 27 to 66 mcg/mL with a median of 43 mcg/mL. The literature suggests 47 to 59 mcg/mL as the range of TBG values expected during the third trimester of pregnancy.

### Cautions

Female individuals using estrogen-based contraception may exceed the reference range.

The drug asfotase alfa (STRENSIQ), a recombinant form of alkaline phosphatase, is expected to interfere with in vitro diagnostic assays with alkaline phosphatase detection systems, such as this assay. Patients taking asfotase alfa should utilize testing with a non-alkaline phosphatase methodology.

### Clinical Reference

1. Burtis CA, Ashwood ER, Bruns DE eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. Elsevier; 2006:2053-2095
2. Wenzel KW. Pharmacological interference with in vitro tests of thyroid function. *Metabolism*. 1981;30(7):717-732

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3. Mimoto MS, Refetoff S. Clinical recognition and evaluation of patients with inherited serum thyroid hormone-binding protein mutations. J Endocrinol Invest. 2020;43(1):31-41. doi:10.1007/s40618-019-01084-9
4. Pappa T, Ferrara AM, Refetoff S. Inherited defects of thyroxine-binding proteins. Best Pract Res Clin Endocrinol Metab. 2015;29(5):735-747

## Performance

### Method Description

The IMMULITE 2000 TBG (thyroxine-binding globulin) is a solid-phase chemiluminescent immunoassay. The solid phase, a polystyrene bead, is coated with a monoclonal antibody specific to TBG. The patient sample and alkaline phosphate-conjugated TBG are added and incubated. During this time, TBG in the sample competes with the enzyme-labeled TBG for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is removed by washing and the chemiluminescent substrate is added. The substrate, a phosphate ester of adamantyl dixetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of the intermediate results in the sustained emission of light. The photon output is inversely proportional to the concentration of the TBG in the sample. (Package insert: IMMULITE 2000 TBG PIL2KTB-16. Siemens Medical Solutions; 03/15/2018)

### PDF Report

No

### Day(s) Performed

Monday, Wednesday, Friday

### Report Available

1 to 3 days

### Specimen Retention Time

2 weeks

### Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

## 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

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manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

84442

**LOINC® Information**

| Test ID | Test Order Name               | Order LOINC® Value |
|---------|-------------------------------|--------------------|
| TBGI    | Thyroxine Binding Globulin, S | 3021-3             |

| Result ID | Test Result Name              | Result LOINC® Value |
|-----------|-------------------------------|---------------------|
| TBGI      | Thyroxine Binding Globulin, S | 3021-3              |