Overview

Useful For
As an adjunct in the diagnosis of autoimmune thyroid diseases: Hashimoto disease, postpartum thyroiditis, neonatal hypothyroidism, and Graves disease.

Identification of potentially unreliable serum thyroglobulin measurements by immunoassay in the follow-up of patients with differentiated follicular-cell derived thyroid carcinomas (for this application order HTG2 / Thyroglobulin, Tumor Marker, Serum or HTGR / Thyroglobulin, Tumor Marker Reflex to LC-MS/MS or Immunoassay).

Method Name
Immunoenzymatic Assay

NY State Available
Yes

Specimen

Specimen Type
Serum Red

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: Red top

Specimen Volume: 0.6 mL

Collection Instructions: Red-top tubes should be centrifuged and aliquoted within 2 hours of collection.

Additional Information: If thyroglobulin tumor marker testing is desired, do not order this test; order HTG2 / Thyroglobulin, Tumor Marker, Serum, which includes both thyroglobulin and thyroglobulin antibody or HTGR / Thyroglobulin, Tumor Marker Reflex to LC-MS/MS or Immunoassay, depending on caregiver’s preference.

Forms
If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

<table>
<thead>
<tr>
<th>Reject Due To</th>
<th>Acceptance</th>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
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<tr>
<td>Other</td>
<td>Gel tube</td>
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Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

Thyroglobulin autoantibodies bind thyroglobulin (Tg), a major thyroid-specific protein. Tg plays a crucial role in thyroid hormone synthesis, storage, and release.

Tg is not secreted into the systemic circulation under normal circumstances. However, follicular destruction through inflammation (thyroiditis and autoimmune hypothyroidism), hemorrhage (nodular goiter), or rapid disordered growth of thyroid tissue, as may be observed in Graves disease or follicular cell-derived thyroid neoplasms, can result in leakage of Tg into the blood stream. This results in the formation of autoantibodies to Tg (anti-Tg) in some individuals. The same processes also may result in exposure of other "hidden" thyroid antigens to the immune system, resulting in the formation of autoantibodies to other thyroid antigens, in particular thyroid peroxidase (TPO) (anti-TPO). Since anti-Tg and anti-TPO autoantibodies are observed most frequently in autoimmune thyroiditis (Hashimoto disease), they were originally considered to be of possible pathogenic significance in this disorder. However, the consensus opinion today is that they are merely disease markers. It is felt that the presence of competent immune cells at the site of thyroid tissue destruction in autoimmune thyroiditis simply predisposes the patient to form autoantibodies to hidden thyroid antigens.

In individuals with autoimmune hypothyroidism, 30% to 50% will have detectable anti-Tg autoantibodies, while 50% to 90% will have detectable anti-TPO autoantibodies. In Graves disease, both types of autoantibodies are observed at approximately half these rates.

The presence of anti-Tg, which occurs in 15% to 30% of thyroid cancer patients, could result in misleading Tg results. In immunometric assays, the presence of thyroid antibody can lead to false-low measurement; whereas it might lead to false-high results in competitive assays.

Reference Values

<4.0 IU/mL

Reference values apply to all ages.

Interpretation

Diagnosis of Autoimmune Thyroid Disease:

Measurements of antithyroid peroxidase (TPO) have higher sensitivity and equal specificity to antithyroglobulin (anti-Tg) measurements in the diagnosis of autoimmune thyroid disease. Anti-Tg levels should, therefore, only be measured if anti-TPO measurements are negative, but clinical suspicion of autoimmune thyroid disease is high. Detection of significant titers of anti-Tg or anti-TPO autoantibodies is supportive evidence for a diagnosis of Graves disease in patients with thyrotoxicosis. However, measurement of the pathogenic antithyroid-stimulating hormone (TSH) receptor antibodies by binding assay (THYRO / Thyrotropin Receptor Antibody, Serum) or bioassay (TSI / Thyroid-Stimulating Immunoglobulin [TSI], Serum) is the preferred method of confirming Graves disease in atypical
cases and under special clinical circumstances.

Positive thyroid autoantibody levels in patients with high-normal or slightly elevated serum thyrotropin levels predict the future development of more profound hypothyroidism.

Patients with postpartum thyroiditis with persistently elevated thyroid autoantibody levels have an increased likelihood of permanent hypothyroidism.

In cases of neonatal hypothyroidism, the detection of anti-TPO or anti-Tg in the infant suggests transplacental antibody transfer, particularly if the mother has a history of autoimmune thyroiditis or detectable thyroid autoantibodies. The neonatal hypothyroidism is likely to be transient in these cases.

Thyroid Cancer Follow-up:

Following therapy of differentiated follicular-cell derived thyroid cancer, patients with no residual thyroid tissue and no persistent or recurrent cancer will have undetectable or very low serum Tg levels. Persistently elevated or rising serum Tg levels, either on or off thyroxine replacement therapy, suggest possible tumor persistence or recurrence. However, if a patient also has measurable anti-Tg autoantibody levels, the results of serum Tg measurements may be unreliable. Anti-Tg may result in both falsely-low and, less commonly, falsely high serum Tg measurements. Therefore, in anti-Tg-positive patients, serum Tg measurements should not be used as the sole measurement for thyroid cancer follow-up and should be interpreted with caution. A thyroglobulin antibody result of <4.0 IU/mL is unlikely to cause clinically significant thyroglobulin assay interference. It is recommended that the thyroglobulin result be reviewed for concordance with clinical presentation.

Cautions

Antithyroglobulin (anti-Tg) and antithyroid peroxidase (anti-TPO) values determined by different methodologies might vary significantly and cannot be directly compared with one another. Some patients might show to be antibody-positive by some methods and antibody-negative by others. Comparing anti-Tg and anti-TPO values from different methods might lead to erroneous clinical interpretation.

Clinical Reference


Performance

Method Description

The Access Thyroglobulin Antibody II assay (TgAb) is a sequential 2-step immunoenzymatic (sandwich) assay. A sample is added to a reaction vessel with paramagnetic particles coated with the thyroglobulin protein. The serum TgAb binds to the thyroglobulin. After incubation in a reaction vessel, materials bound to the solid phase are held in place by a magnetic field, while unbound materials are washed away. The thyroglobulin-alkaline phosphatase conjugate is added and binds to the TgAb. After the second incubation, materials bound to the solid phase are held in place by a magnetic field, while unbound materials are washed away. Then, the chemiluminescent substrate, LumiPhos 530 is added to the reaction vessel and light generated by the reaction is measured with a luminometer. The
light production is directly proportional to the concentration of thyroglobulin antibody in the sample. (Instruction manual: Thyroglobulin Antibody II Assay, Beckman Coulter, Inc., Fullerton, CA 2011)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Friday 6 a.m.-12 a.m.
Saturday 6 a.m.-6 p.m.

**Analytic Time**
Same day/1 day

**Maximum Laboratory Time**
3 days

**Specimen Retention Time**
3 months

**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 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**
86800

**LOINC® Information**

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