Test Definition: TGAB

Thyroglobulin Antibody, Serum

Overview

Useful For

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

Highlights

In conjunction with antithyroperoxidase autoantibodies, this test aids in the evaluation of autoimmune thyroiditis (Hashimoto disease).

Method Name

Immunoenzymatic Assay

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Ordering Guidance

For the follow-up of patients with differentiated follicular cell-derived thyroid carcinomas, consider either HTG2 / Thyroglobulin, Tumor Marker, Serum or HTGR / Thyroglobulin, Tumor Marker Reflex, Serum.

The preferred method for confirming Graves disease in atypical cases or under special clinical circumstances is measurement of the pathogenic antithyrotropin receptor antibodies by binding assay or bioassay. Order either THYRO / Thyrotropin Receptor Antibody, Serum or TSI / Thyroid-Stimulating Immunoglobulin, 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)
Container/Tube: Red top (gel tubes/**SST are not acceptable)**
Submission Container/Tube: Plastic vial
Specimen Volume: 0.6 mL serum
Collection Instructions: Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Forms

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

Specimen Minimum Volume

Serum: 0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	Reject

Specimen Stability Information

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

Clinical & 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.

Thyroglobulin 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 that 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). 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 of 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 antithyroperoxidase (anti-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 antithyrotropin receptor antibodies by binding assay (THYRO / Thyrotropin Receptor Antibody, Serum) or bioassay (TSI / Thyroid-Stimulating Immunoglobulin, 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. Neonatal hypothyroidism is likely to be transient in these cases.

Cautions

Low titers of thyroid autoantibodies may be observed in the absence of autoimmune or other thyroid diseases and are considered a nonspecific finding. The population prevalence of such nonspecific low-level antithyroglobulin (antiTg) positivity is higher in female patients than in male patients and increases with age in both sexes.

Patients with nodular thyroid disease who are antithyroid autoantibody positive may have coexisting Hashimoto disease, which can result in a suspicious fine-needle aspiration biopsy diagnosis of follicular or Hurthle cell neoplasia.

Anti-Tg and antithyroperoxidase (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.

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. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1 Sapin P, d'Herbomez M, Gasser F, Meyer L, Schlienger JL. Increased sensitivity of a new assay for anti-thyroglobulin antibody detection in patients with autoimmune thyroid disease. Clin Biochem. 2003;36(8):611-616. doi:10.1016/s0009-9120(03)00114-0
2. Saravanan P, Dayan CM. Thyroid autoantibodies. Endocrinol Metab Clin North Am. 2001;30(2):315-337
3. Baloch Z, Carayon P, Conte-Devolx B, et al. Laboratory Medicine Practice Guidelines. Laboratory support for the

diagnosis and monitoring of thyroid disease Thyroid. 2003;13(1):3-126
4. Soh SB, Aw TC. Laboratory testing in thyroid conditions - Pitfalls and clinical utility. Ann Lab Med. 2019;39(1):3-14. doi:10.3343/alm.2019.39.1.3
5. Spencer C, Fatemi S. Thyroglobulin antibody (TgAb) methods - Strengths, pitfalls and clinical utility for monitoring TgAb-positive patients with differentiated thyroid cancer. Best Pract Res Clin Endocrinol Metab. 2013;27(5):701-712. doi:10.1016/j.beem.2013.07.003
6. Netzel BC, Grebe SK, Carranza Leon BG, et al. Thyroglobulin (Tg) testing revisited: Tg assays, TgAb assays, and correlation of results with clinical outcomes. J Clin Endocrinol Metab. 2015;100(8):E1074-83. doi:10.1210/jc.2015-1967
7. Algeciras-Schimnich A. Thyroglobulin measurement in the management of patients with differentiated thyroid cancer. Crit Rev Clin Lab Sci. 2018;55(3):205-218. doi:10.1080/10408363.2018.1450830
8. Netzel BC, Grebe SK, Algeciras-Schimnich A. Usefulness of a thyroglobulin liquid chromatography-tandem mass spectrometry assay for evaluation of suspected heterophile interference. Clin Chem. 2014;60(7):1016-1018. doi:10.1373/clinchem.2014.224816
9. Wassner AJ, Della Vecchia M, Jarolim P, Feldman HA, Huang SA. Prevalence and significance of thyroglobulin antibodies in pediatric thyroid cancer. J Clin Endocrinol Metab. 2017;102(9):3146-3153. doi:10.1210/jc.2017-00286
10. Frohlich E, Wahl R: Thyroid autoimmunity: Role of anti-thyroid antibodies in thyroid and extra-thyroidal diseases. Front Immunol. 2017;8:521. doi:10.3389/fimmu.2017.00521

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 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. Thyroglobulin-alkaline phosphatase conjugate is added and binds to the TgAb. After a second incubation, materials bound to the solid phase are held in place by a magnetic field, while unbound materials are washed away. Then, chemiluminescent substrate is added to the reaction vessel, and light generated by the reaction is measured with a luminometer.(Package insert: Access Thyroglobulin Antibody II. Beckman Coulter Inc; 04/2020)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

14 days

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

CPT Code Information

86800

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
TGAB	Thyroglobulin Antibody, S	56536-6

Result ID	Test Result Name	Result LOINC® Value
TGAB	Thyroglobulin Antibody, S	56536-6