

NEW TEST TEST CHANGE

NOTIFICATION DATE: 08/21/2024

EFFECTIVE DATE: 09/10/2024

Thyroglobulin Antibodies (anti-Tg)

On the effective date, Northwell Health Laboratories will implement a change in the assay methodology for the measurement of thyroglobulin autoantibodies (anti-Tg), as part our continued commitment to providing state-of-the-art clinical diagnostic testing service. The current chemiluminescence immunoassay (Siemens IMMULITE 2000 Anti-Tg Ab) will be replaced with an electrochemiluminescence immunoassay (Roche ELECSYS Anti-Tg).

Thyroglobulin autoantibodies are frequently elevated in individuals with autoimmune thyroid diseases. Specifically, these autoantibodies are present in 80-90% of Hashimoto's disease (autoimmune thyroiditis) patients and 50-70% of Graves' disease patients. Furthermore, approximately 25% of differentiated thyroid cancer (DTC) patients also exhibit anti-Tg autoantibodies. Measuring anti-Tg concentration is crucial in the post-thyroidectomy monitoring of DTC patients, as these autoantibodies can interfere with assays for thyroglobulin measurement. [1]

An in-house method comparison study conducted at Northwell Health Laboratories demonstrated acceptable qualitative clinical concordance between the two assays. ***However, it is important to note that due to differences in immunoassay design and antibody epitope recognition, direct comparison of quantitative values between the two assays is not feasible.*** Please be aware of this change in methodology when reviewing patient histories and previous anti-Tg results, particularly for patients undergoing serial monitoring. Adjustments in clinical interpretation is necessary, as highlighted in the table below.

Test Requirement	New	Previous
Methodology	Electrochemiluminescence Immunoassay	Chemiluminescence immunoassay
Assay Manufacturer	Roche Diagnostics	Siemens Healthineers
Result Interpretation	≤ 115 IU/mL: Negative > 115 IU/mL: Positive	≤ 40 IU/mL: Negative > 40 U/mL: Positive
Specimen Collection	1 mL Serum (0.5 mL minimum)	1 mL Serum (0.5 mL minimum)
Computer Interface Code	PDM #5900116	PDM #5900116
Test Order	ATYGL	ATYGL

If you have any questions, please contact Client Services at (800) 472-5757.

References:

1. Luca Giovannella et al. Thyroglobulin and thyroglobulin antibody: an updated clinical and laboratory expert consensus. *European Journal of Endocrinology*, Volume 189, Issue 2, August 2023, Pages R11–R27, <https://doi.org/10.1093/ejendo/lvad109>