

NEW TEST  TEST CHANGE

NOTIFICATION DATE: 08/22/2024

EFFECTIVE DATE: 09/10/2024

## Change In Thyroglobulin Assay Methodology

Effective 9/10/2024, Northwell Health Laboratories will transition to a new assay methodology for thyroglobulin (Tg) measurement. This update is driven by recent instrument enhancements, demonstrating our commitment to providing superior laboratory services. The current chemiluminescence immunoassay (Siemens IMMULITE 2000 Thyroglobulin) will be replaced with an electrochemiluminescence immunoassay (Roche ELECSYS Tg II).

Thyroglobulin, a thyroid-specific glycoprotein synthesized by follicular cells, is crucial in thyroid hormone synthesis. Measurement of thyroglobulin concentration is recommended for monitoring of persistence or recurrence/metastatic disease in patients with differentiated thyroid cancer (DTC) after total thyroidectomy (with or without radioiodine ablative therapy). [1] Note that thyroglobulin autoantibodies can significantly interfere with thyroglobulin measurement; therefore, thyroglobulin autoantibodies should be measured concurrently with serum thyroglobulin. [1,2]

An in-house method comparison study conducted at Northwell Health Laboratories demonstrated a strong positive correlation ( $R = 0.95$ ) between the two assays. *However, direct comparison of quantitative result values between the two assays is not feasible due to variability in immunoassay design and antibody epitope recognition.* Please be aware of this change in methodology when reviewing patient histories and previous thyroglobulin results, particularly for patients undergoing serial monitoring post thyroidectomy. 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
Reference Interval	<b>0.90 – 77.30 ng/mL</b>	1.60 – 59.90 ng/mL
Specimen Collection	1 mL Serum (0.5 mL minimum)	1 mL Serum (0.5 mL minimum)
Computer Interface Code	<b>PDM #5900117</b>	<b>PDM #5900117</b>
Test Order	<b>TYGL</b>	<b>TYGL</b>

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

### References:

1. Haugen, Bryan R., et al. "2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer." *Thyroid* 26.1 (2016): 1-133. <https://doi.org/10.1089/thy.2015.0020>
2. Luca Giovanella et al. *European Journal of Endocrinology*, Volume 189, Issue 2, August 2023, Pages R11–R27, <https://doi.org/10.1093/ejendo/ivad109>

