Thyroglobulin Testing in Differentiated Thyroid Cancer



Thyroid Cancer at a Glance: Rising Incidence, Mortality, and Patient Profile

Thyroid cancer (TC) incidence has risen steadily over recent decades, making it the seventh most commonly diagnosed cancer worldwide with an incidence of 821,214 cases, while its impact on cancer-related mortality remains substantially lower, ranking 24th among all cancers.[1] In the U.S., incidence increased by more than 200% between 1992 and 2018, even as mortality rates remained largely stable, despite over 60,000 newly diagnosed cases each year.[2] This contrasted situation between the rising incidence of TC, and the relatively stable disease-specific mortality is largely explained by the typically indolent nature of many thyroid malignancies and by broader use of advanced diagnostic imaging and high-resolution neck ultrasonography which have enabled earlier detection of thyroid nodules and smaller tumors. Unlike many adult cancers, TC is often diagnosed at a younger age, with cases commonly identified in middle adulthood, and it affects women about three times more often than men. Although TC can occur across all age groups, disease behavior is generally more aggressive in patients older than 55.[3,4]



Why Accurate Tumor Classification Matters in Clinical Practice

From a biological and clinical perspective, TC comprises a heterogeneous group of tumors that differ in cellular origin, disease course, prognosis, and management strategies. Accurate histopathological classification of tumor tissue—obtained through biopsy—is crucial because TC subtype directly informs treatment decisions, biomarker selection, and long-term disease monitoring.[3]

Differentiated Thyroid Cancer: The Predominant Disease Subtype

Differentiated thyroid cancer (DTC) including papillary thyroid carcinoma (≈84% of all TC), follicular thyroid carcinoma (≈4%), and oncocytic carcinoma (≈2%) arises from thyroid follicular cells and accounts for about 90% of all thyroid malignancies.[5,6] Papillary thyroid carcinoma is typically associated with an indolent disease course, although certain variants and high-risk presentations require more intensive management.[6] Follicular thyroid carcinoma, the second most common subtype, is also a well-differentiated malignancy but is generally associated with a more aggressive biological profile than papillary cancer, including a greater tendency for distant metastases.[2,6] By contrast, medullary thyroid carcinoma constitutes a distinct and relatively uncommon form of TC (≈4%) and a separate neuroendocrine entity with unique biological characteristics, biomarker profiles, and clinical management pathways. Therefore, it is not classified as DTC.

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Post Treatment Follow Up in DTC: ATA Framework and Role of Thyroglobulin

DTC is the main driver of the global rise in TC incidence. As risk-adapted care has become increasingly important, post-treatment surveillance and response-to-therapy assessment have become central components of DTC management. The 2025 American Thyroid Association (ATA) Management Guidelines for Adult Patients with Differentiated Thyroid Cancer[7] outline this approach through the DATA framework for clinical management.

This framework spans the patient's journey from diagnosis through long-term follow-up. Within this framework, serum biomarkers—particularly thyroglobulin (Tg), play an important role in guiding follow-up and determining when additional evaluation may be warranted.[7] (See Insert 1 for guidance on when Tg measurement is, and is not, recommended under the 2025 ATA guidelines).

Thyroglobulin: A Biological Marker with Clinical Value in DTC Surveillance

Thyroglobulin (Tg) is a large, high-molecular-weight (~660 kDa) iodinated glycoprotein produced exclusively by thyroid follicular cells and stored within the follicular lumen as a major component of the thyroid colloid. It is the essential precursor and structural substrate for thyroid hormone biosynthesis, as thyroid peroxidase catalyzes the iodination of tyrosyl residues within the Tg molecule, allowing the formation and storage of thyroxine (T4) and triiodothyronine (T3). Upon thyroid stimulation, iodinated thyroglobulin undergoes regulated endocytosis and intracellular proteolysis, leading to the release of T4 and T3 into the circulation.

Because thyroglobulin is exclusively produced by thyroid follicular cells and co secreted with thyroid hormones, measurement of serum Tg has emerged as a sensitive and practical tumor marker for postoperative thyroid follow up. It plays a central role in the surveillance of DTC by enabling biochemical detection of persistent or recurrent disease after thyroidectomy, with or without radioactive iodine (RAI) therapy. Monitoring frequency should be individualized based on risk stratification and clinical context. (See insert 1 for ATA recommendations)

After total thyroidectomy with or without RAI, Tg concentrations are expected to be very low or undetectable. Rising Tg levels—especially under TSH suppression—may indicate persistent or recurrent disease and should prompt further evaluation including imaging.

Laboratory Measurement of Thyroglobulin in DTC Surveillance

Tg levels were historically primarily measured with competitive radioimmunoassays (RIA) using polyclonal antibodies. Over the years easy-to-use automated conventional immunometric assays (Tg-IMAs), using monoclonal antibodies, became routinely available in many clinical laboratories.[8] Then, the "second generation" of these Tg-IMAs, or high-sensitivity Tg immunometric assays (hsTg IMAs), could measure very low Tg concentrations (functional sensitivity / concentration measured with ≤ 20% CV ≤ 0.1 ng/mL), thereby eliminating frequently the need for TSH stimulation often required with older and less sensitive Tg assays.[9]

Table 1 below, adapted from a recent publication from the "hsTg & TgAb Consensus Working Group"[10], provides an overview of the Tg-IMAs currently available on the market.

Manufacturer	Tg assay	Principle
Abbott	Architect Tg	CLIA
Abbott	Alinity i Tg	CLIA
Beckman Coulter	Access Tg	CLIA
BRAHMS Thermofisher	BRAHMS h-Tg Sensitive KRYPTOR	TRACE
Diasorin	Liaison® Tg II Gen	CLIA
Roche Diagnostics AG	Elecsys Tg II	ECLIA
Siemens Healthineers	Atellica® IM Tg	CLIA
Siemens Healthineers	Immulite 2000 Tg	CLIA

Both the "hsTg & TgAb Consensus Working Group"[10] and the 2025 ATA guidelines[7]—strongly recommends using Tg assays calibrated against the BCR®457 reference standard. However, they both emphasize that even with standardization, inter-method variability can persist across assays—potentially confounding longitudinal trend interpretation and clinical decision-making during patients monitoring. For that reason, they strongly recommend performing patients longitudinal Tg monitoring with the same manufacturer's assay and, whenever possible, within the same laboratory.[7,10] If a change in methodology is unavoidable, a new baseline should be established on the new testing platform before subsequent results are interpreted.[10]

Concordance of three of the hsTg-IMAs available on the market has been recently investigated by La Civita et al who evaluated on 103 samples the Siemens Healthineers Atellica IM Tg, Beckman Coulter Access Tg (defined as the reference method) and DiaSorin Liaison TgII Gen assays.[11] The authors reported a very strong overall correlation across those three methods, although correlation was influenced by Tg concentrations. In the case of the Access Tg and Atellica IM Tg assays, an overall concordance of 98% for negative results was observed (48 of 49 samples testing negative on both assays). The two assays demonstrated a very strong overall correlation for the overall cohort with a Spearman coefficient – $\rho = 0.92$, $p < 0.0001$ with the strongest correlation observed for Tg concentrations between 2 and 50 ng/mL ($\rho = 0.96$, $p < 0.0001$). In contrast, only moderate to strong correlations were reported at concentrations above 50 ng/mL ($\rho = 0.74$, $p = 0.0003$) and lower correlations at concentrations between 0 and 2 ng/mL ($\rho = 0.53$, $p < 0.0001$). Taken together with the comparative analyses of the other methods, the study showed overall good concordance among the methods evaluated, with some variability across different Tg concentration ranges.

In addition, accuracy of serum Tg measurements can be significantly affected by anti thyroglobulin antibodies (TgAb), which can be detected in approximately 25% of patients with DTC.[12,13] TgAb interference remains a major limitation to the clinical utility of Tg as a tumor marker, as it may lead to either falsely low or falsely high Tg results depending on the assay methodology used. With Tg-IMAs, underestimation of Tg concentrations is commonly observed because TgAb may block the specific epitopes targeted by monoclonal antibodies. Although LC-MS/MS assays reduce analytical interference from TgAb, studies have not consistently demonstrated superior clinical sensitivity compared with high-sensitivity immunometric assays.[14,15] Accordingly, the "hsTg & TgAb Consensus Working Group"[10] recommends hsTg-IMAs over conventional Tg assays for monitoring patients with DTC, together with a quantitative TgAb test for each Tg measurement to identify potentially unreliable results. The figure 1 summarizes their suggested algorithms to monitor patients with and without TgAb.[10]

Figue 1 TgAb-negative and positive patients

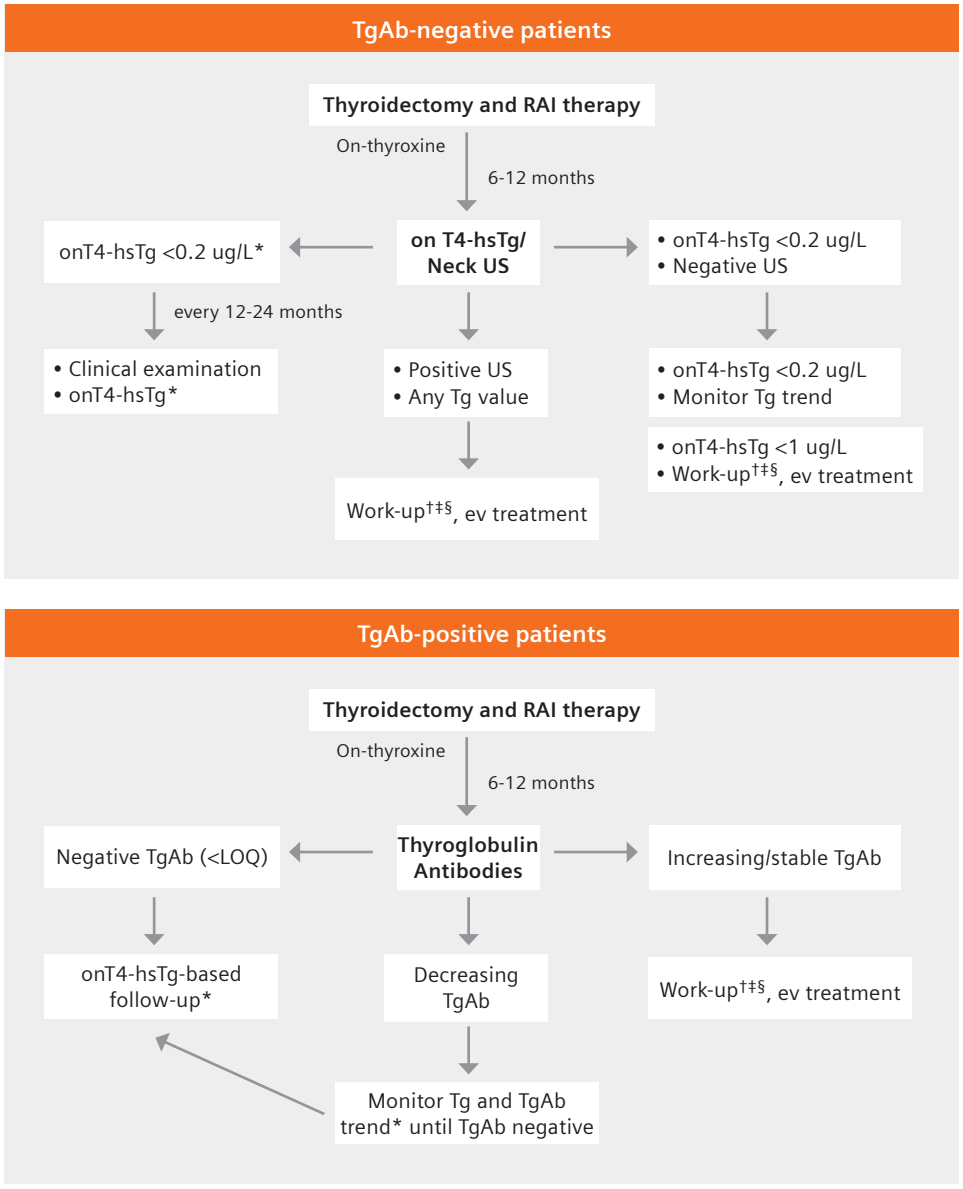


Figure 1. Proposed hsTg-based follow-up algorithm for DTC patients who are negative for TgAb (above) or positive for TgAb (below). Extracted from[10]. hsTg, highly-sensitive thyroglobulin measurement; LOQ, limit of quantification; on T4, measurement taking during continuing intake of levothyroxine; RAI, radioiodine; TgAb, serum autoantibodies against thyroglobulin; US, ultrasound.

* Can be combined with neck US (not mandatory)
† Radioiodine whole body scintigraphy (selective, second-line)
‡ Computed tomography, magnetic resonance, positron emission tomography (selective, third-line)
§ Neck US in all cases

TgAb levels typically decline after successful treatment and increase with DTC progression;[9] as a result, their longitudinal changes and trends are increasingly used as a surrogate and prognostic tumor marker in TgAb-positive patients, in whom Tg measurements may be unreliable.[9,16-17] In this setting, falling TgAb levels may indicate a decreasing tumor burden or remission, stable TgAb levels may suggest stable disease, and rising TgAb levels may signal persistent or recurrent disease requiring further evaluation. As with Tg, TgAb measurements should be performed using the same assay and preferably within the same laboratory to ensure reliable trend interpretation.

Insert 1: What Serum Tg Is and Is Not Used For in DTC *(Adapted from ATA 2025 Guidelines[7])*

According to the 2025 ATA guidelines, serum Tg and TgAb testing do not play a role in the diagnosis of DTC, which emphasize cytopathology, imaging, molecular testing, and clinical or familial risk factors rather than biochemical tumor markers.

Accordingly, routine preoperative Tg/TgAb testing is not recommended **(Recommendation 9)**, and routine testing is also not advised during active surveillance** **(Recommendation 13)**. In the preoperative setting, Tg assessment has only limited interest, as fine needle aspiration Tg (FNA Tg) washout may be added selectively in the evaluation of suspicious cervical lymph nodes, although interpretation can be challenging when the thyroid gland remains intact **(Recommendation 7C)**.

In contrast, serum Tg measurement becomes a central biochemical tool in postoperative management of DTC. The ATA recommends a structured approach beginning with application of the 2025 ATA Risk Stratification System, which integrates histopathologic features, American Joint Committee on Cancer (AJCC) staging, postoperative imaging, and biochemical assessments, including Tg and TgAb measurements when appropriate **(Recommendation 28A)**. Following surgery, the ATA Response-to-Therapy framework†† should be applied in combination with recurrence-risk estimates to guide the intensity of subsequent treatment and surveillance **(Recommendation 29)**.

Within this framework, Tg supports both early assessment and long term monitoring. After total thyroidectomy, the ATA recommends measuring serum Tg 6–12 weeks postoperatively—either while on thyroid hormone therapy or following TSH stimulation‡‡—to define an early biochemical reference point **(Recommendation 30A)**. Serial Tg measurement on thyroid hormone therapy, with or without radioactive iodine (RAI), is recommended to monitor response to therapy and detect recurrence, with higher predictive value after RAI **(Recommendation 47B)**.

After thyroid lobectomy in patients with normal TSH, a single early Tg measurement is considered good practice to confirm that Tg is not unexpectedly elevated, although no definitive cutoff is established **(Recommendation 30B)**; however, ATA doesn't recommend longitudinal Tg monitoring during follow-up after lobectomy while on thyroid hormone **(Recommendation 47D)**.

For follow up after total thyroidectomy, Tg should be measured with assays calibrated against the BCR® standard, with a quantitative TgAb determination done for each Tg measurement **(Recommendation 47A)**. Testing is typically done every 6–12 months, with more frequent testing considered in patients at intermediate high or high risk of recurrence **(Recommendation 47C)**. In patients with TgAb, serial TgAb trends using the same assay may provide supportive information§§ for disease monitoring. Since Tg measurements by different methodologies (IMAs, RIAs) are often unreliable in these patients or have low sensitivity (LC-MS/MS), imaging remains the primary modality for disease surveillance, with cervical ultrasound preferred and additional imaging guided by Tg/TgAb findings, risk, and response to therapy **(Recommendations 47E, 31A–C)**.

Beyond surveillance, Tg trends may also inform management decisions in patients without structurally demonstrable disease***. In those patients, stimulated serum Tg <10 ng/mL after thyroid hormone withdrawal or <5 ng/mL with rhTSH may be managed conservatively with thyroid hormone therapy alone, reserving additional treatment for rising Tg levels over time or other evidence of disease progression **(Recommendation 58A)**. In contrast, empiric or dosimetry-guided RAI therapy may be considered in patients with more markedly elevated or rapidly increasing serum Tg levels, particularly when imaging remains negative for disease amenable to directed therapy **(Recommendation 58B)**.

** **Active surveillance** is an imaging based follow up of selected low risk intrathyroidal DTC as an alternative to upfront surgery; not applicable to persistent or recurrent disease.
†† **Response to therapy:** ATA response categories (excellent, indeterminate, biochemical incomplete, structural incomplete) based on Tg/TgAb trends and imaging findings.
‡‡ **Stimulated vs on therapy Tg:** Stimulated Tg is measured after TSH stimulation (thyroid hormone withdrawal or rhTSH); on therapy Tg is measured during thyroid hormone therapy.
§§ **TgAb positive patients:** Tg measurements may be unreliable; serial TgAb trends (same assay) may provide supportive information but do not replace imaging.
*** **Structurally demonstrable disease:** Disease identified on imaging, irrespective of serum Tg levels.

In summary:

What serum Tg is used for

- Postoperative risk stratification and response assessment within the ATA management framework (Recommendations 28A, 29)
- Providing an early postoperative biochemical reference after total thyroidectomy (6–12 weeks postoperatively, on thyroid hormone therapy or after TSH stimulation (Recommendation 30A)
- Long term monitoring of response to therapy and detection of recurrence after total thyroidectomy, with or without radioactive iodine (RAI), with higher predictive value after RAI (Recommendation 47B)
- Guiding the intensity of surveillance and management escalation based on trends in Tg over time, in conjunction with imaging (Recommendations 29, 47C)
- Informing management decisions in patients without structurally demonstrable disease, including continued observation versus escalation of therapy based on Tg kinetics (Recommendations 58A, 58B)

What serum Tg is not used for

- Diagnosis of thyroid cancer, where evaluation relies on cytopathology, imaging, molecular testing, and clinical or familial risk factors (Diagnostic Recommendations 1–5)
- Routine preoperative evaluation of patients with suspected thyroid cancer (Recommendation 9)
- Routine biochemical monitoring during active surveillance (Recommendation 13)
- Routine longitudinal follow up after thyroid lobectomy in patients on thyroid hormone therapy (Recommendation 47D)
- Sole disease monitoring in patients with circulating TgAb, in whom Tg measurements are frequently unreliable (Recommendation 47E)

Selective or limited uses

- **FNA Tg washout** may be used selectively in the preoperative evaluation of suspicious cervical lymph nodes, with cautious interpretation when the thyroid gland remains intact (Recommendation 7C)
- **Serial TgAb trends** (using the same assay) may provide supportive information on disease status but should always be interpreted in conjunction with imaging (Recommendation 47E)

About the Atellica IM Thyroglobulin (Tg) and Atellica IM aTgII

The **Atellica IM Thyroglobulin (Tg)** assay is for in vitro diagnostic use in the quantitative measurement of thyroglobulin in human serum and plasma (EDTA and lithium heparin) using the Atellica IM and Atellica CI analyzers. This assay is a high-sensitivity second-generation Tg-IMA with a measuring range of 0.050 to 150.000 ng/mL (0.076–227.250 pmol/L) and detection capability was determined in accordance with CLSI Document EP17-A2.[18-20]

- Limit of Blank (LoB): 0.040 ng/mL (0.061 pmol/L)
- Limit of Detection (LoD): 0.046 ng/mL (0.070 pmol/L)
- Limit of Quantitation (LoQ): 0.050 ng/mL (0.076 pmol/L)

The assay standardization is traceable to the Community Bureau of Reference (BCR®) Certified Reference Material (CRM) 457[19,20] and no hook effect was observed up to 80,000 ng/mL (121,200 pmol/L).[19,20]

The **Atellica IM Anti-Thyroglobulin II (aTgII)** assay is for in vitro diagnostic use in the quantitative measurement of autoantibodies against thyroglobulin in human serum and plasma (EDTA, lithium heparin, sodium heparin) using the Atellica IM and Atellica CI analyzers.[21,22]

This assay's measuring range is 1.6 to 1000 IU/mL and its detection capability was determined in accordance with CLSI Document EP17-A2.[18]

- Limit of Blank (LoB): 1.2 IU/ml
- Limit of Detection (LoD): 1.6 IU/ml
- Limit of Quantitation (LoQ): 1.6 IU/ml

The assay standardization is traceable to the World Health Organization (WHO) International Reference Preparation for Anti-Thyroglobulin Serum, Human (NIBSC 65/093).[21,22]

Since TgAb can be found in approximately 25% of patients with DTC,[12,13] Siemens Healthineers internal studies[23] demonstrated that the Atellica IM Tg assay provides reliable Tg measurements when Atellica IM aTgII concentrations are below 10 IU/mL. In this range, antibody interference does not meaningfully affect Tg measurement.

When Atellica IM TgAb levels are ≥10 IU/mL, Tg immunometric assay results may be falsely low and should be interpreted with caution for clinical decision making and therefore Atellica IM Tg results may be affected by antibody interference, and using the trend of Atellica IM TgAb measurements could then become the preferred option.

Clinical Situation	Recommended Assay	Interpretation
TgAb < 10 IU/mL	Atellica IM Tg + Anti Tg	Tg result is reliable; monitor Tg trend
TgAb ≥ 10 IU/mL	Atellica IM Anti Tg	Tg result may be unreliable; monitor TgAb trend. Imaging remains primary
Low risk, post thyroidectomy	Atellica IM Tg + Anti Tg	On therapy Tg result usually sufficient; stimulated Tg reserved for selected cases
High risk or rising markers	Atellica IM Tg + Anti Tg	Rising Tg or TgAb → investigate with imaging and consider management escalation
Lobectomy only	Atellica IM Tg + Anti Tg	Tg largely reflects remnant thyroid tissue, and routine longitudinal Tg monitoring is not recommended.

Conclusion

For clinicians and laboratorians involved in thyroid cancer management, high-sensitivity second-generation Tg-IMA assays can provide meaningful support in the postoperative surveillance of DTC. The Atellica IM Tg assay is designed to detect Tg in human serum and plasma and can be used as an aid in monitoring DTC patients who have undergone thyroidectomy with or without radioiodine ablation.

When used in combination with the Atellica Anti-Tg assay, these assays may support clinicians in the monitoring of patients with differentiated thyroid cancer (DTC), particularly in the presence of TgAb, which may interfere with Tg measurements.

Disclaimer: The product/feature and/or service offerings mentioned herein are not commercially available in all countries and/or for all modalities. Their future availability cannot be guaranteed.

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23. Data on file

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