

Client Communication

# Change in Instrumentation and Methodology: Thyroglobulin Antibody and Thyroid Peroxidase Antibody

**Effective May 8, 2023**

Pathology Laboratories, Inc. (PathLabs) is in the process of making updates to our Test Directory based on changes being made by our reference laboratory partner, Clinical Pathology Laboratories (CPL), a Sonic Healthcare USA, Inc. affiliate of Austin, Texas.

Effective May 8, 2023, PathLabs is pleased to announce that CPL will change its analytic platform and method for Thyroglobulin Antibody (Anti-Tg) and Thyroid Peroxidase Antibody (Anti-TPO). The new methodology is electrochemiluminescence immunoassay (ECLIA).

The change in instrumentation and methodology will result in changes to reference range and the clinical reporting range of the two (2) assays as specified below. All changes are shown in **bright blue**:

### Reference Range Changes:

Assay	Current Reference Range	New Reference Range
Thyroglobulin AB	< 4 IU/mL	<b>&lt;= 115 IU/mL</b>
Thyroid Peroxidase AB	< 9 IU/mL	<b>&lt;= 34 IU/mL</b>

### Clinical Reporting Range Changes:

Assay	Current Clinical Reporting Range	New Clinical Reporting Range
Thyroglobulin AB	1 - 2200 IU/mL	<b>10 - 4000 IU/mL</b>
Thyroid Peroxidase AB	1 - 900 IU/mL	<b>9 - 600 IU/mL</b>

In summary, the **platform and methodology change** exclusively affects the **reference range** and the **clinical reporting range** of the two (2) assays. Specimen requirements, CPT Codes, throughput and database mapping remain the same.

**Important Note:** Thyroglobulin AB values determined on patient samples by different testing procedures cannot be directly compared with one another and can cause erroneous medical interpretations. Re-baselining of patients may be required in some cases and will be offered by PathLabs in conjunction with CPL at provider request. CPL will also maintain the current analytic platform and methodology for 30 days after the above effective date.

## Client Communication

Thyroglobulin (Tg) is produced in the thyroid gland and is a main component in the lumen of the thyroid follicle. In synergy with the enzyme thyroid-specific peroxidase (TPO), Tg has an essential function in the iodination of L-tyrosine and in the formation of the thyroid hormones T4 and T3.

Thyroid-specific peroxidase (TPO) is synthesized in the endoplasmic reticulum, where it is folded to its native state and undergoes core glycosylation, before being transported to the apical plasma membrane of thyrocytes.

The detection of anti-TPO and anti-Tg are considered diagnostic markers of autoimmune thyroid disorders. The prevalence of these two antibodies is high in patients with Graves' disease and Hashimoto's thyroiditis.

Name	Order Code
Thyroglobulin AB RFLX EIA vs LCMS	38936
Thyroglobulin AB	36690
Thyroid Peroxidase AB	75068/389734
Thyroid Antibody Group (TPO + TG)	37437
Thyroglobulin, Quantitative and Antibody	36700
Thyroid Cascade Reflex	38973

Our online test directory will be updated to reflect this information on May 8, 2023.

This Client Communication will be posted to our website for reference.

Please review the information and make changes as applicable to your practice/facility. If you have any questions, please contact our Client Service Department at 419.255.4601/800.281.8804 or your account executive. Thank you.

### References:

Fröhlich E, Wahl R. Thyroid Autoimmunity: Role of Anti-thyroid Antibodies in Thyroid and Extra-Thyroidal Diseases. *Front Immunol.* 2017 May 9;8:521. doi: 10.3389/fimmu.2017.00521. PMID: 28536577; PMCID: PMC5422478.

Ghosh R, Chatterjee S, Dubey S, Pandit A, Ray BK, Benito-León J. Anti-Thyroid Peroxidase/Anti-Thyroglobulin Antibody-Related Neurologic Disorder Responsive to Steroids Presenting with Pure Acute Onset Chorea. *Tremor Other Hyperkinet Mov (N Y).* 2020 Jul 8;10:19. doi: 10.5334/tohm.175. PMID: 32775033; PMCID: PMC7394228.