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# The Upper Reference Limit For Thyroid Peroxidase Autoantibodies Is Method-Dependent. A Collaborative Study With Biomedical Industries

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## Abstract

*Background.* The determination of the upper reference limit (URL) for thyroid peroxidase autoantibodies (TPOAbs) is a contentious issue, because of the difficulty in defining the reference population. The aim of this study was to establish the URL (eURL) for TPOAbs, according to the National Academy of Clinical Biochemistry (NACB) guidelines and to compare them with those obtained in a female counterpart, by the use of six commercial automated platforms.

*Methods.* 120 healthy males and 120 healthy females with NACB-required characteristics (< 30 years, TSH between 0.5 and 2.0 mIU/L, normal thyroid ultrasound, without personal/family history of thyroid and non-thyroid autoimmune diseases) were studied. Sera were analyzed for TPOAbs concentration using six immunoassay methods applied in automated analyzers: Advia Centaur XP (CEN), Siemens Healthcare Diagnostics; Maglumi 2000 Plus, Shenzen New Industries Biomedical Engineering; Architect ci4100, Abbott; Cobas e411 (COB) Roche Diagnostics; Unicel DxI (UNI) and Lumipulse G1200, Fujirebio.

*Results.* Within each method, TPOAbs values had a high degree of dispersion and the eURLs were lower than those stated by the manufacturer. A statistically significant difference ($p < 0.05$) between medians of males and females was observed only for COB and for UNI. However, the comparison of the male and female proportions positive for TPOAbs using the eURL of the counterpart, showed the lack of clinical significance of the above differences (Chi-square test, $p > 0.05$).

*Conclusions.* Despite the analytical harmonization, the wide dispersion of the results and the differences of the eURLs between methods suggest the need of further studies focusing on TPO antigen preparations as the possible source of variability between different assays. In addition, the lack of clinical significant difference between males and females, in terms of TPOAb eURLs, confirms the suitability of the NACB recommendations.