

# HIGH SENSITIVITY OF A NEW METHOD FOR THE DETERMINATION OF ANTI-THYROID PEROXIDASE AUTOANTIBODIES ON AUTOMATIC ANALYZER MAGLUMI: TOWARDS THE FOURTH GENERATION OF IMMUNOASSAYS?

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## Aim of the study

Third generation automated methods for anti-thyroid peroxidase autoantibodies (TPOAb) measurement show a relevant difference in analytical and functional sensitivity, and in the reference intervals stated by manufacturers. The aim of the study was the evaluation of TPOAb concentrations on the automated analyzer Maglumi in a reference population, selected according to National Academy of Clinical Biochemistry (NACB) guidelines<sup>1</sup>.

## Materials and methods

120 subjects were selected according to NACB guidelines (male, younger than 30 years, biochemically euthyroid, with no goiter, no personal/family history of thyroid disease and without non-thyroid autoimmune diseases) (Table 1 and Figure 1).

TPOAb were determined with a chemiluminescent automated method on Maglumi 2000 Plus analyzer (SNIBE, Shenzhen, China) (Figure 2).

Analytical sensitivity (Limit of Detection) was defined as TPOAb concentration corresponding to the mean plus 2 standard deviations of 20 replicates of the zero standard.

The results were expressed as median with range (min-max) and the upper reference limit (URL) was established at 97.5<sup>th</sup> percentile. A two-sided value of  $p < 0.05$  was considered statistically significant.

Statistical analyses were performed by GraphPad Prism (GraphPad Prism Software, San Diego, CA, USA).

Class	No.	Fraction (%)	Age* (yrs)
0-10 yrs	20	17	8.0 ± 2.1
11-15 yrs	30	25	13.1 ± 1.5
16-20 yrs	18	15	17.2 ± 1.2
21-25 yrs	21	17	23.1 ± 1.1
26-30 yrs	31	26	28.3 ± 1.5
0-30 yrs	120	100	18.6 ± 7.5

Table 1. Classes of age.  
\*Mean ± Standard Deviation

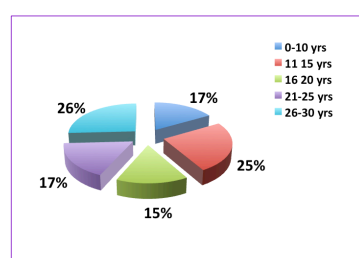


Figure 1. Schematic representation of age classes.

## Results

Median was 2.2 IU/mL (0.2-27.4) and URL was 19.8 IU/mL, lower than 30.0 IU/mL, stated by the manufacturer (Table 2).

Instrument	No.	Median	CV (%)	Min	Max	97.5 p	Suggested cut-off
Maglumi 2000 Plus	120	2.2	123.8	0.15	27.4	19.8	30.0

Table 2. Main statistical parameters of TPOAb in the reference population. TPOAb values are expressed as IU/mL.

Value distribution was not Gaussian with a positive skew, as described in literature. Only 27% of subjects exhibited TPOAb concentrations  $\leq 0.15$  IU/mL (analytical sensitivity), unlike what happens with more established and frequently used methods (>50-60%) (Figure 3).

Data obtained in our study confirmed the analytical sensitivity declared by the manufacturer.

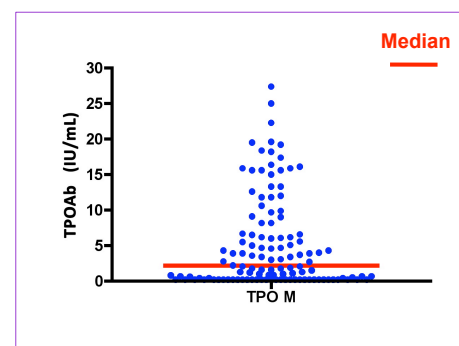


Figure 3. Distribution of TPOAb values in the reference population.

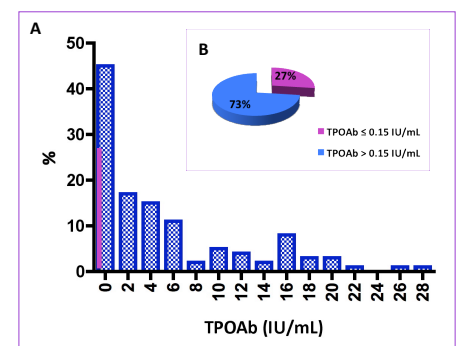


Figure 4. TPOAb frequency distribution in the reference population (A) and fraction of subjects exhibiting TPOAb concentrations lower than the analytical sensitivity (B).

## Discussion and conclusions

The new automated method showed a high analytical sensitivity and was therefore able to measure TPOAb concentrations in most of the samples obtained from healthy subjects. For this reason, methods with analytical sensitivity of less than 1 IU/mL, such as that used on Maglumi analyzer, could be considered as the fourth generation.

## References

1. Baloch Z, Carayon P, Conte-Devolx B, Demers LM, Feldt-Rasmussen U, Henry JF, LiVosli VA, Niccoli-Sire P, John R, Ruf J, Smyth PP, Spencer CA, Stockigt JR; Guidelines Committee, National Academy of Clinical Biochemistry. Laboratory medicine practice guidelines. Laboratory support for the diagnosis and monitoring of thyroid disease. *Thyroid*. 2003;13:3-126.