



Novel TSH assays display highly significant correlation with symptoms of hypothyroidism as well as with adverse effects in patients under levothyroxine therapy

Catherine Ronin

e-mail id: catherine.ronin@siamed-tech.com

Work over the past decades has assigned changes in TSH glycosylation to the onset of hypothyroidism. However, most current assays fail to accurately measure such diseased forms of TSH and more than often, TSH level does not correlate with clinical signs of hypothyroidism. To achieve a better assessment of TSH level, we developed a glycoengineered calibrator mimicking highly sialylated TSH and screened antibodies accordingly to construct new assays. All these assays showed harmonized TSH measurements (84 patients with TSH 2.1-22.4 mIU/L).

Clinical validation of 4 of these new assays was carried out on a cohort of 1363 patients (18-85y) with TSH between 0.1 -63mIU/L without TRAK or anti-TPO antibodies. FT3, FT4 and 11 clinical signs of hypothyroidism were also recorded. New assays showed a positive correlation between TSH level and clinical signs in 797 healthy subjects according to gender (M/F) and age (<60y and >60y).

A cohort of 253 patients under T4 treatment, with clinical symptoms and adverse effects was also studied. In untreated individuals, the ratio new assay/IRMA decreased as the number of major signs increased, indicating that each assay can bind a different set of TSH forms as the number of clinical signs increase. In T4-treated patients, 5 major hypothyroid signs were found to be reduced by T4 treatment and 3 adverse effects were increased while 26.3% of the patients did not present normal TSH values.

TSH new assays may therefore serve as a therapy test to identify subclinical hypothyroidism, initiate and adjust hormonal treatment.

References:

Variability among TSH measurements can be reduced by combining a glycoengineered calibrator to epitope-defined immunoassays. Donadio-Andréi S, Chikh K, Heuclin C, Kuczewski E, Charrié A, et al. (2017) Eur Thyr J 6:3-11. doi: 10.1159/000449463

New Immunoassays of Bioactive TSH Improve Detection of Thyroid Disorders
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Subclinical Hypothyroidism: is it Really Subclinical with Aging?

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