Hytest

Thyroid Diseases

Antibodies and antigens

Introduction

The thyroid is an endocrine gland that stimulates hormones, which are tightly linked to the regulation of energy. Its interrelationship with the hypothalamus and pituitary glands forms a feedback loop, which controls and balances the body's metabolism. Thyroid diseases are among the most common endocrine disorders globally, and while they can be life-threatening in some cases, they are usually curable and treatable. This makes the diagnosis of thyroid diseases very important.

Hytest offers a vast range of antibodies and antigens to enable our customers to develop their assays for thyroid diseases. Furthermore, we continue to develop new products that we introduce to the market, and our products are trusted by customers worldwide.

More detailed information regarding the performance of our products, a full list of individual MAbs and recommendations for capture-detection antibody pairs (when available) can be found on our website — www.hytest.fi.

You are also most welcome to contact our Sales Team directly by writing to

hytest@hytest.fi.

Thyroid stimulating hormone (TSH)

CLINICAL UTILITY

- **Thyroid dysfunction**
- **Thyroid management and screening during pregnancy, postpartum, and for newborns**

TSH is the first-line marker for assessing thyroid function, and it is widely used in the evaluation of hyperthyroidism. Functional sensitivity at very low TSH concentrations is a key performance criterion for fourth-generation TSH immunoassays. Building on our established portfolio, we have developed novel sheep monoclonal antibodies (MAbs) for high-sensitivity TSH assay development.

Product highlights for novel sheep MAbs

- Ultra-low TSH quantification: Novel sheep MAbs enable the quantification of extremely low TSH concentrations in human serum. Prototype immunoassays using these antibodies achieved a functional sensitivity of < 0.001 µIU/mL. A high correlation (Pearson's correlation coefficient > 0.99) was observed between TSH concentrations determined using prototype immunoassays and the Roche Elecsys TSH assay. Representative results are presented in Fig. 1.
- R55G variant coverage: The antibodies recognize both the TSH R55G variant and wild-type TSH. This enables accurate detection in serum samples from individuals carrying the R55G mutation (see Fig. 2).
- High specificity: There is no cross-reactivity with other glycoprotein hormones (see Fig. 3).

Hytest also offers recombinant TSH antigen that is designed to closely mimic the native form.

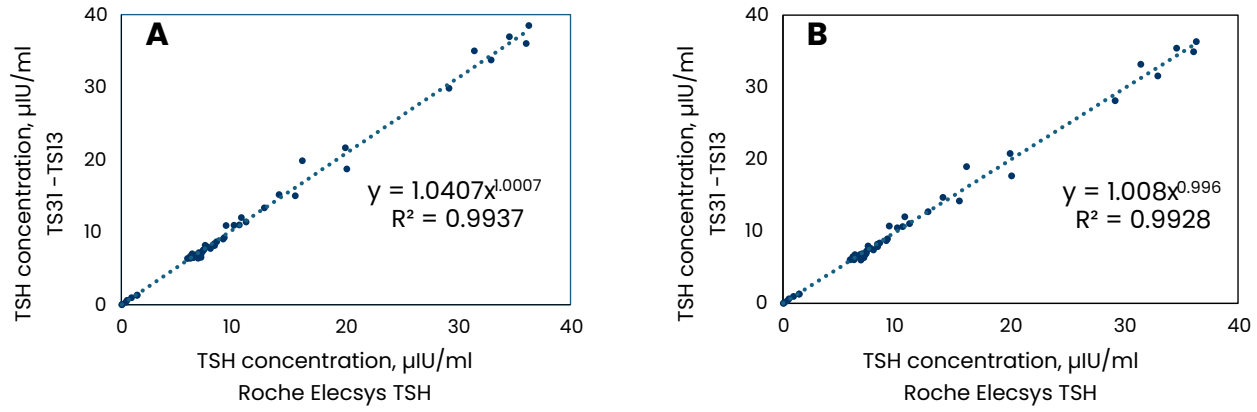

Figure 1.
TSH concerntrations were determined in human serum samples using recommeded MAb combinations TS31-TS13 (A), TS21-TS18 (B) and the reference assay Roche Elecys TSH. Sample volume: 30 µl. Incubation time: 19 min. Incubation temperature: +37°C.

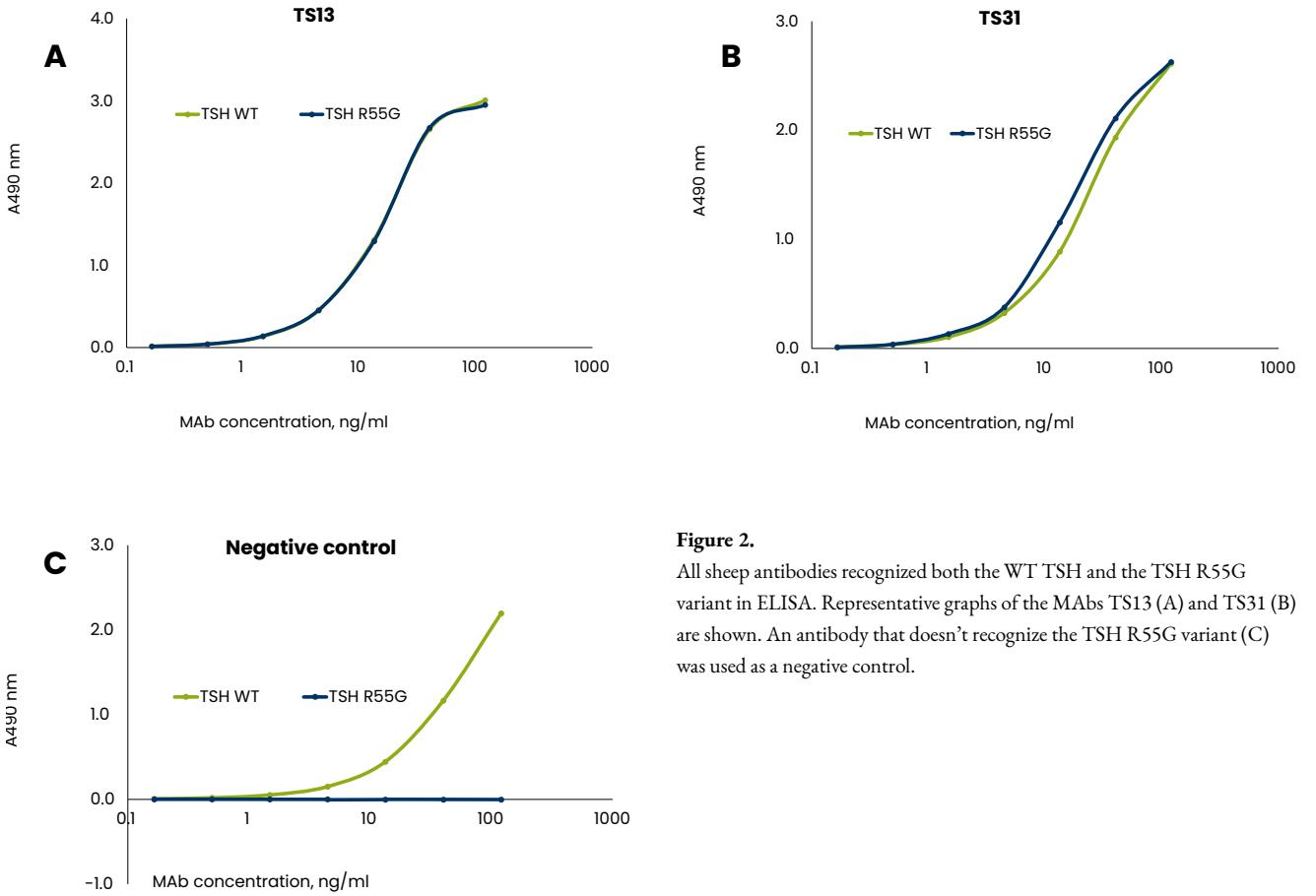

Figure 2.
All sheep antibodies recognized both the WT TSH and the TSH R55G variant in ELISA. Representative graphs of the MAbs TS13 (A) and TS31 (B) are shown. An antibody that doesn't recognize the TSH R55G variant (C) was used as a negative control.

MONOCLONAL ANTIBODIES

Cat. #	Product name	Tested applications
2TS11cc* 2TS11	Thyroid stimulating hormone (TSH)	Chemiluminescence immunoassay Enzyme immunoassays Western blotting

***Note.**
Several MABs available under one catalogue number. Please visit www.hytest.fi

ANTIGENS

Product name	Cat. #	MAb	Remarks
Thyroid-stimulating hormone (TSH), human, recombinant	8HTS7	95%	Recombinant

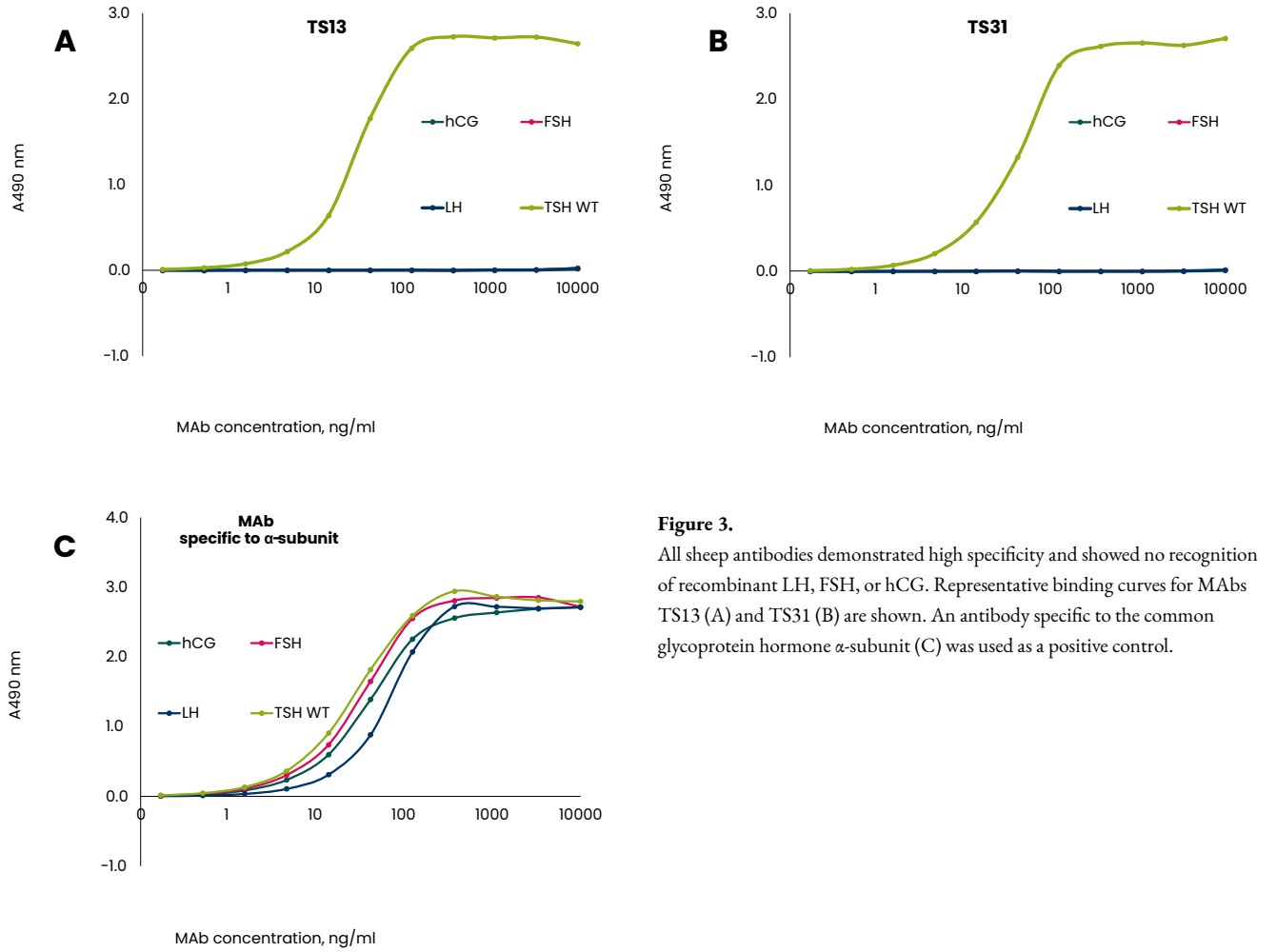

Figure 3.
All sheep antibodies demonstrated high specificity and showed no recognition of recombinant LH, FSH, or hCG. Representative binding curves for MAbs TS13 (A) and TS31 (B) are shown. An antibody specific to the common glycoprotein hormone α-subunit (C) was used as a positive control.

Thyroglobulin (Tg) and Thyroglobulin antibodies (TgAb)

CLINICAL UTILITY

- **Differentiated thyroid diseases (DTC)**
- **Autoimmune thyroid diseases (AITD)**

Thyroglobulin (Tg) testing is primarily used for follow-up of patients with differentiated thyroid cancer (DTC) after total thyroidectomy and radioactive iodine ablation. Tg testing supports the assessment of residual or metastatic disease. Prototype assays using Hytest's Tg antibodies (TG12, TG14, TG16, TG23, TG33, TG36, TG37, TG46, TG47, TG64) show no detectable interference from thyroglobulin autoantibodies (TgAb), achieve high sensitivity (≤ 0.02 ng/mL) on a CLIA platform (see Fig. 4 for a representative curve of the recommended antibody pairs), and demonstrate a strong correlation with commercially available assays (see Fig. 5).

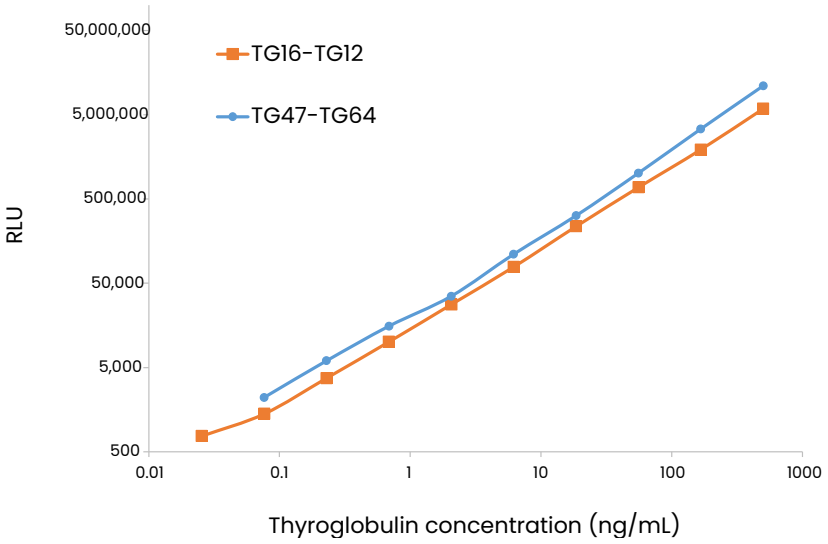

Figure 4.
Calibration curves for immunoassays TG47-TG64 and TG16-TG12. A mixture of capture antibodies labeled with biotin, antigen, and detection antibodies labeled with alkaline phosphatase was incubated for 15 minutes at 37°C. The luminescent signal is expressed in Relative Light Units (RLUs).

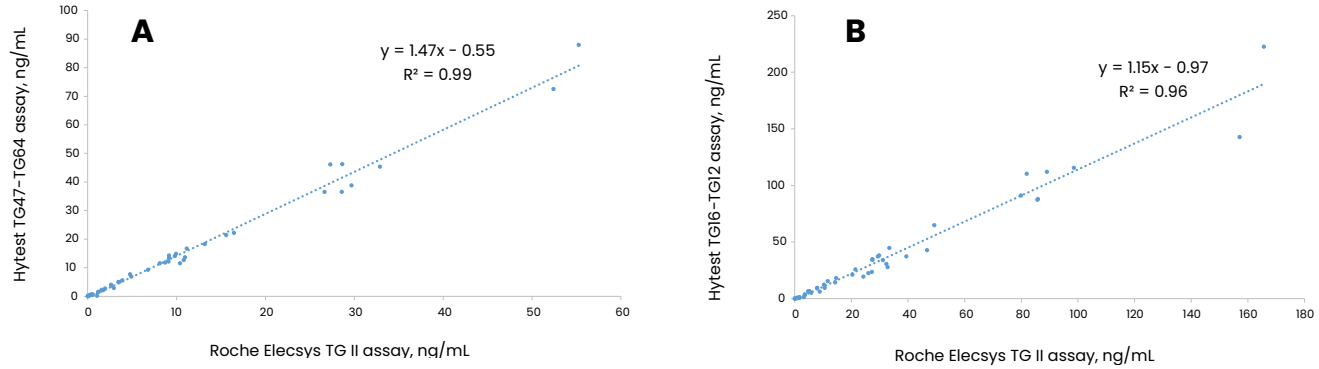

Figure 5.

A scatter plot of thyroglobulin levels measured in 50 serum samples with two immunoassays based on the MAb pairs TG47-TG64 (A) and TG16-TG12 (B) in comparison with the Roche Elecsys TG II assay. A mixture of capture antibodies labelled with biotin, calibrator, or serum samples, and detection antibodies labelled with alkaline phosphatase was incubated for 15 minutes at 37°C.

Anti-thyroglobulin (TgAb). Elevated serum concentrations of TgAb are commonly observed in autoimmune thyroid diseases (AITDs), including Graves' disease and Hashimoto's thyroiditis. A negative TgAb result can help in terms of ruling out Hashimoto's thyroiditis in the appropriate clinical context. TgAb assays are also commonly used in conjunction with Tg assays for the monitoring of patients with DTC.

TG08, TG51, and TG61 are intended for the development of immunoassays for the quantitative determination of anti-thyroglobulin antibodies. This is because these MAbs target thyroglobulin epitopes that are recognized by autoantibodies. TG08, TG51, and TG61 can be used individually in competitive immunoassays. Furthermore, TG08 or TG61 can be combined with the supplemental antibody TG66 in competitive formats; the recommended primary-to-supplemental antibody ratio is 3:1. Notably, using a mixture of TG08 (primary) with TG66 (supplemental), or TG61 (primary) with TG66 (supplemental) at a 3:1 ratio increased correlation with the Roche Elecsys anti-Tg assay ($R^2 > 0.9$).

MONOCLONAL ANTIBODIES

Cat. #	Product name	Tested applications
2TG12cc*	Thyroglobulin	Enzyme immunoassays Western blotting Immunohistochemistry

***Note.**

Several MABs available under one catalogue number. Please visit www.hytest.fi

ANTIGENS

Product name	Cat. #	Purity	Source
Thyroglobulin	8TG52	>90%	Human thyroid gland
Thyroglobulin, recombinant	8RTG4	>95%	Recombinant

Thyroid peroxidase (TPO)

TPO is one type of thyroid antibody that could be related to autoimmune thyroid diseases. Clinically, if the TPO antibody value is high, the patient is potentially at risk of Hashimoto's or post-partum primary hypothyroidism diseases. Furthermore, recent studies have presented the associations of thyroid autoimmunity with infertility. At Hytest, we provide high-quality monoclonal antibodies and recombinant antigen for TPO assay development.

MONOCLONAL ANTIBODIES

Cat. #	Product name	Tested applications
4TP15*	Thyroid peroxidase (TPO)	Enzyme immunoassays Western blotting

***Note.**

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ANTIGEN

Product name	Cat. #	Purity	Source
Thyroid peroxidase (TPO), recombinant	8RTP0	>95%	Recombinant

Thyroxin (T4) and Triiodothyronine (T3)

T4 is the major thyroid hormone secreted by the thyroid gland. Through the removal of an iodine atom, T4 is converted to T3 in the circulation. T4 and T3 are often measured either as a total form (total T4 and total T3) or a free form (free T4 and free T3) in combination with TSH as thyroid function tests for diagnosis in the clinical setup. At Hytest, we provide high-quality monoclonal antibodies for T4 and T3 assay development.

MONOCLONAL ANTIBODIES

Cat. #	Product name	Tested applications
2T6*	Thyroxin, human (T4)	Enzyme immunoassays Radioimmunoassay
2T7	Triiodothyronine (T3)	

***Note.**

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More information

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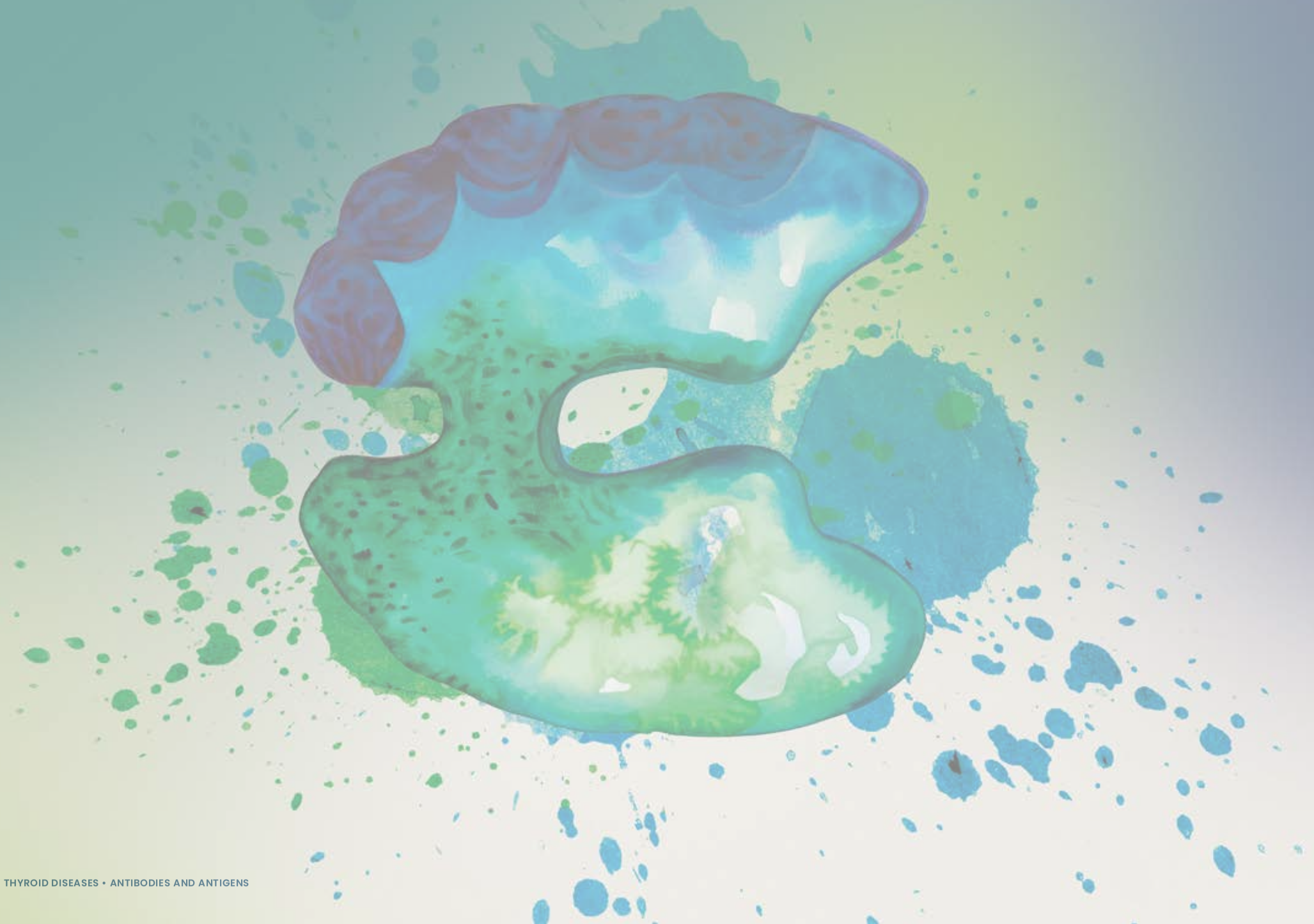

THYROID DISEASES • ANTIBODIES AND ANTIGENS

Hytest

Scientific excellence for IVD

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