

Radioimmunoassay (RIA/IRMA) Product Portfolio



Product Highlights

- Gold standard assays for Type 1 Diabetes and Thyroid Diagnostics
- Excellent diagnostic efficiency with high sensitivity and specificity
- High precision within the measurement range

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Importance in the Diagnosis of Diabetes mellitus Type 1

Diabetes mellitus Type 1

Diabetes mellitus type 1 is a chronic autoimmune disease in which the insulin-producing beta cells of the islets of Langerhans in the pancreas are destroyed. The consequence of this destruction is a reduced insulin production, which results in high blood sugar levels as diabetes mellitus. Genetic predispositions and viral infections are considered risk factors, but the exact causes have not yet been fully clarified.

Islet Cell Antibodies

The destruction of the insulin-producing beta cells of the pancreas is based on the presence of islet cell antibodies (ICA), which are directed against different antigens of the pancreatic islet cells, such as glutamic acid decarboxylase (GAD₆₅), tyrosine phosphatase (insulinoma-associated antigen 2, IA2), the zinc transporter 8 (ZnT8) and against insulin (IAA). Islet cell antibodies (ICA) can be detected in 70 – 80 % of patients with diabetes mellitus. The different antibodies usually appear months to years before the occurrence of elevated blood sugar levels and are therefore also considered important prognostic markers to identify patients with an increased risk of developing diabetes mellitus type 1. The combined detection of antibodies against GAD₆₅, IA2, ZnT8, insulin or ICA is considered an important method for diagnosing diabetes mellitus type 1 at the onset of the disease.

Antibodies against Insulin (IAA)

The appearance of antibodies against insulin (IAA) is an indication of the progressive destruction of insulin-producing pancreatic beta cells in patients with diabetes mellitus type 1. Their prevalence is particularly increased in children and adolescents who have not yet been treated with insulin.

Antibodies against Glutamate Decarboxylase (GAD₆₅)

Glutamic acid decarboxylase (GAD) catalyzes the synthesis of the neurotransmitter GABA in the brain and in the beta cells. Two isoforms of the enzyme, GAD₆₅ with a molecular weight of 65 kDa and GAD₆₇ with 67 kDa, are known. Antibodies directed against GAD₆₅ are observed in the majority of patients with diabetes mellitus type 1 and in a large number of individuals in the prediabetic phase. In contrast, antibodies directed against both GAD isoforms are found in patients with the very rare neuromuscular Stiff-man syndrome.

Antibodies against Tyrosine Phosphatase (IA2)

Protein tyrosine phosphatase (insulinoma-associated antigen 2, IA2) is localized in the granules of pancreatic beta cells. Antibodies against IA2 can be detected in the majority of patients with diabetes mellitus type 1 and in a large number of individuals in the prediabetic phase. The appearance of antibodies against the IA2 is correlated with rapid progression of diabetes mellitus type 1.

CentAK® IAA M – Radioimmunoassay for the quantitative determination of antibodies against Insulin (IAA)

Analytical Sensitivity and Specificity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Detection (LoD) was assessed by multiple analysis of negative samples. The Limit of Quantitation (LoQ) was correlated to an intraassay coefficient of variation of 10 % and an interassay coefficient of variation of 20 %. The high quality of the tracer ensures the exclusive reaction of anti-IAA autoantibodies in the assay.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	< 0.12 U/mL
Limit of Detection (LoD)	0.12 U/mL
Limit of Quantitation (LoQ)	0.20 U/mL

Diagnostic Sensitivity and Specificity

The sensitivity and specificity were assessed by the analysis of 21 samples of diabetes type 1 patients and 45 samples of non-selected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	> 99 %
Specificity	> 99 %

CentAK® Anti GAD₆₅ M – Radioimmunoassay for the quantitative determination of antibodies against Glutamic Acid Decarboxylase (GAD65)

Analytical Sensitivity and Specificity

The Limit of Quantitation (LoQ) was correlated to an intraassay coefficient of variation of 10 % and an inter-assay coefficient of variation of 20 %. The high quality of the tracer ensures the exclusive reaction of anti-GAD₆₅ autoantibodies in the assay.

	ANALYTICAL PERFORMANCE
Limit of Quantitation (LoQ)	0.70 U/mL

Diagnostic Sensitivity and Specificity

The sensitivity and specificity were assessed by the analysis of 65 samples of diabetes type 1 patients and 392 samples of non-selected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	86.2 %
Specificity	96.7 %

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CentAK[®] anti-IA₂ M – Radioimmunoassay for the quantitative determination of antibodies against Protein Tyrosine Phosphatase (IA2)

Analytical Sensitivity

The Limit of Quantitation (LoQ) was correlated to an intraassay coefficient of variation of 10 % and an interassay coefficient of variation of 20 %. The high quality of the tracer ensures the exclusive reaction of anti-IA2 autoantibodies in the assay.

	ANALYTICAL PERFORMANCE
Limit of Quantitation (LoQ)	0.8 U/mL

Diagnostic Sensitivity and Specificity

Sensitivity and specificity were assessed by the analysis of serum samples from 42 patients with diabetes mellitus type I and 41 samples from unselected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	88 %
Specificity	95 %



Importance in the Diagnosis of Thyroid Disorders –

A key aspect in autoimmune diagnostics

Thyroid Disorders

Thyroid disorders are prevalent endocrine conditions resulting from the dysregulation of thyroid hormone production. The thyroid gland synthesizes two key hormones: FT4 (Free Thyroxine) and FT3 (Free Triiodothyronine), which are essential for regulating metabolism, growth, and development. The secretion of these hormones is regulated by TSH (Thyroid-Stimulating Hormone), produced by the anterior pituitary gland. Disruptions in this feedback loop, whether through intrinsic thyroid gland dysfunction or autoimmune mechanisms, can lead to either hypothyroidism or hyperthyroidism. Autoimmune thyroid diseases, such as Hashimoto's thyroiditis and Graves' disease, are frequently implicated, with the presence of antibodies such as anti-TPO (Thyroid Peroxidase Antibodies) and anti-Tg (Thyroglobulin Antibodies) serving as key diagnostic markers.

Epidemiology

Autoimmune Thyroid disorders are highly prevalent worldwide, affecting approximately 2-5% of the population, with a higher incidence in women. The prevalence of thyroid autoimmunity also increases with age and is influenced by genetic and environmental factors, including iodine intake and smoking.

Diagnosis

The diagnostic approach to thyroid disorders includes biochemical assays and immunological markers:

TSH: The most sensitive marker for thyroid dysfunction. Elevated TSH suggests primary hypothyroidism, while low levels of TSH indicates hyperthyroidism.

FT3 and FT4: Direct measurement of circulating free hormones is essential in confirming thyroid dysfunction. Low FT3 and/or FT4 with elevated TSH indicates primary hypothyroidism, while elevated FT3 and/or FT4 with suppressed TSH confirms hyperthyroidism.

Anti-TPO and Anti-Tg Antibodies: In autoimmune thyroid disorders, anti-TPO antibodies are frequently elevated in Hashimoto's thyroiditis, indicating an autoimmune attack on thyroid peroxidase, a critical enzyme in thyroid hormone synthesis. Anti-Tg antibodies, targeting thyroglobulin, are also often elevated in Hashimoto's but may interfere with thyroglobulin measurement in post-thyroidectomy cancer patients.

TSH Receptor Antibodies (TRAb): These antibodies are pivotal in the diagnosis of Graves' disease. TRAb either stimulate or block the TSH receptor, with stimulating TRAb being characteristic of Graves' disease, leading to hyperthyroidism. Thyroid disorders, particularly those with an autoimmune component, are common and can lead to significant clinical morbidity if left undiagnosed. The assessment of specific marker is central to the diagnosis, enabling appropriate clinical management and monitoring.

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SELco® FT3 – Radioimmunoassay for the quantitative determination of Free Triiodothyronine (FT3)

Calibration

The immunoassay SELco® FT3 is calibrated using an internal reference sample. Quantitative results are expressed in pmol/L or pg/mL.

Analytical Sensitivity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Detection (LoD) and the Limit of Quantitation (LoQ) were assessed by multiple analysis of negative samples.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	0.43 pmol/mL
Limit of Detection (LoD)	0.78 pmol/mL
Limit of Quantitation (LoQ)	1.35 pmol/mL

SELco® FT4 – Radioimmunoassay for the quantitative determination of Free Thyroxine (FT4)

Calibration

The immunoassay SELco® FT4 is calibrated using an internal reference sample. Quantitative results are expressed in pmol/L or pg/mL.

Analytical Sensitivity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Detection (LoD) and the Limit of Quantitation (LoQ) were assessed by multiple analysis of negative samples.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	0.92 pmol/mL
Limit of Detection (LoD)	1.28 pmol/mL
Limit of Quantitation (LoQ)	1.40 pmol/mL



SELco® anti-TPO human – Radioimmunoassay for the quantitative determination of antibodies against Thyroid Peroxidase (TPO)

Calibration

The immunoassay SELco® anti-TPO human is calibrated using the NIBSC reference preparation NIBSC code 66/387. Quantitative results are expressed in IU/mL.

Analytical Sensitivity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Detection (LoD) and the Limit of Quantitation (LoQ) were assessed by multiple analysis of negative samples.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	< 2.4 IU/mL
Limit of Detection (LoD)	2.4 IU/mL
Limit of Quantitation (LoQ)	12.0 IU/mL

SELco® anti-Tg human – Radioimmunoassay for the quantitative determination of antibodies against Thyroglobulin (Tg)

Calibration

The immunoassay SELco® anti Tg human is calibrated using the NIBSC reference preparation NIBSC code 65/93. Quantitative results are expressed in IU/mL.

Analytical Sensitivity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Detection (LoD) and the Limit of Quantitation (LoQ) were assessed by multiple analysis of negative samples.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	< 8.6 IU/mL
Limit of Detection (LoD)	8.6 IU/mL
Limit of Quantitation (LoQ)	13.0 IU/mL

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SELco® TRAb human 1 step – Radioimmunoassay for the quantitative determination of antibodies against the TSH Receptor (TRAb)

Antigen and Antibody

The SELco® TRAb human 1 step immunoassay is based on a competitive reaction of antibodies against the TSH receptor (TRAb) of the patient samples with a limited amount the iodinated monoclonal antibodies against the TSH receptor for the immobilized human TSH receptor on the solid phase of the coated tubes.

Calibration

The SELco® TRAb human 1 step radioimmunoassay is calibrated using the international standard preparation NIBSC code 08/204. Quantitative results are expressed in IU/L.

Diagnostic Sensitivity and Specificity

Sensitivity and specificity of the immunoassay were assessed by the analysis of 101 samples from patients with Graves' disease and 64 samples from unselected blood donors.

	DIAGNOSTIC PERFORMANCE
Sensitivity	98 %
Specificity	> 99 %

Analytical Sensitivity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Detection (LoD) and the Limit of Quantitation (LoQ) were assessed by multiple analysis of negative samples.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	0.01 IU/L
Limit of Detection (LoD)	0.38 IU/L
Limit of Quantitation (LoQ)	0.90 IU/L



SELco® TSH rapid – Radioimmunoassay for the quantitative determination of Thyrotropin (TSH)

Calibration

The SELco® TSH rapid immunoassay is calibrated using the International Reference Preparation WHO 3rd IRP 81/565. Quantitative results are expressed in mIU/L.

Analytical Sensitivity and Specificity

The Limit of Blank (LoB) was determined by multiple analysis of sample diluent. The Limit of Quantitation (LoQ) was assessed by multiple analysis of negative samples. There is no high dose hook effect up to an hTSH concentration of 8000 μ IU/mL. The monoclonal antibodies used in this IRMA kit are specific for hTSH.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	0.015 mIU/L
Limit of Detection (LoD)	0.036 mIU/L
Limit of Quantitation (LoQ)	0.070 mIU/L



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Importance in the Diagnosis of Thyroid Cancers –

A key aspect in autoimmune diagnostics

Thyroglobulin (Tg) and **Calcitonin** are essential biomarkers in the evaluation of specific thyroid cancers. Tg, a protein produced by thyroid follicular cells, is primarily used to monitor differentiated thyroid cancer (DTC), while calcitonin, secreted by C-cells, is a critical marker for medullary thyroid carcinoma (MTC). Both markers provide insight into tumor burden, disease recurrence, and prognosis in thyroid cancer patients.

Epidemiology

Differentiated Thyroid Cancer (DTC), including papillary and follicular thyroid cancers, accounts for the majority of thyroid malignancies. Thyroglobulin is used as a marker for recurrence in patients post-thyroidectomy and radioactive iodine treatment.

Medullary Thyroid Carcinoma (MTC), originating from parafollicular C-cells, represents 3-5% of thyroid cancers. Calcitonin is elevated in almost all cases of MTC and is particularly useful for early detection, especially in familial syndromes like Multiple Endocrine Neoplasia type 2 (MEN 2).

Diagnosis

Biomarkers are critical for monitoring disease progression and guiding therapeutic interventions in thyroid cancer:

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Thyroglobulin (Tg): Tg levels are measured in patients treated for DTC to detect recurrence. Elevated Tg post-thyroidectomy suggests residual thyroid tissue or metastatic disease. Anti-Tg antibodies should be checked, as they can interfere with Tg measurements.

Calcitonin: Elevated calcitonin is a hallmark of MTC, used for both diagnosis and postoperative surveillance. Persistently high or rising calcitonin levels after surgery indicate residual disease or recurrence. Calcitonin stimulation tests can enhance diagnostic accuracy in borderline cases.

hTG [I-125] IRMA KIT – Radioimmunoassay for the quantitative determination of Thyroglobulin (Tg)

Calibration

The hTG [I-125] IRMA KIT immunoassay is calibrated using the first International Tg Reference Material CRM 457 (Community Bureau of Reference, BCR, European Union, Brussels, Belgium). Quantitative results are expressed in ng/m.

Analytical Sensitivity

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined consistent with the guidelines in CLSI document EP17.

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	0.025 ng/mL
Limit of Detection (LoD)	0.10 ng/mL
Limit of Quantitation (LoQ)	0.20 ng/mL

hCalcitonin [I-125] IRMA KIT – Radioimmunoassay for the quantitative determination of Calcitonin (hCT)

Calibration

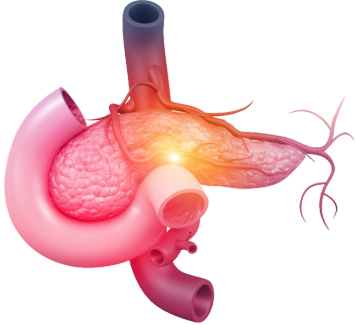
The hCalcitonin [I-125] IRMA KIT immunoassay is calibrated using the International WHO Reference Preparation 89/620. Quantitative results are expressed in pg/mL.

Analytical Sensitivity

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined consistent with the CLSI guidelines, document EP17. The functional sensitivity is equal to the Limit of Quantitation (LoQ).

	ANALYTICAL PERFORMANCE
Limit of Blank (LoB)	0.65 pg/mL
Limit of Detection (LoD)	1.21 pg/mL
Limit of Quantitation (LoQ)	2.00 pg/mL

Radioimmunoassays (RIA /IRMA)



Type 1 Diabetes

Test	Reference	Determinations
CentAK® IAA M	2035	100
CentAK® anti-IA2 M	2050	50
CentAK® anti-IA2 M	2150	100
CentAK® anti-GAD65 M	2070	100
CentAK® anti-GAD65 M	2071	50

Thyroid Diseases

Test	Reference	Determinations
SELco® TSH rapid	1450	100
SELco® FT3	1652	100
SELco® FT4	1881	100
SELco® TRAb human 1 step	2042	100
SELco® anti-TPO human	2080	100
SELco® anti-Tg human	2085	100

Tumor Markers

Test	Reference	Determinations
hTG [I-125] IRMA KIT	RK-51CT	100
hCalcitonin [I-125] IRMA KIT	RK-83CT	100

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