

Type 1 Diabetes Assays

Serological determination of antibodies against
ICA / GAD₆₅ / IA2 / Insulin (IAA) in human serum



CE

Product Highlights

- Serological marker for autoimmune diabetes mellitus type 1
- Excellent diagnostic efficiency with high sensitivity and specificity
- Automatable on common open systems
- Available for several lab methods (ELISA, RIA, IFA)

YOUR RELIABLE PARTNER IN AUTOIMMUNE DIAGNOSTICS

Over 30 Years of Experience, 150 Partners in more than 100 Countries

Antibodies against ICA / GAD₆₅ / IA2 / IAA

and their 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.

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 are known, GAD₆₅ with a molecular weight of 65 kDa and

GAD₆₇ with 67 kDa. 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 IA2 is correlated with rapid progression of diabetes mellitus type 1.

Antibodies against Insulin (IAA)

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

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. Depending on the age of the patient, different autoantibody testing strategies are used.

Immunoassays for the Determination of IgG Antibodies against - ICA / GAD₆₅ / IA2 / IAA in human Serum

ICA IFA / AKLIDES® ICA

ICA IFA and AKLIDES® ICA are immunoassay slides are coated with monkey pancreas tissue sections for both tests. ICA IFA is indicated for visual evaluation, whereas AKLIDES® ICA is specifically designed for automated imaging using an akirno® NEO system.

DIAGNOSTIC PERFORMANCE	
Sensitivity	> 90 %
Specificity	> 99 %

Medizym® Anti-IA₂ M /

CentAK® anti-IA2 M

The Medizym® anti-IA2 M and CentAK® anti-IA2 M are immunoassays for the determination of antibodies against Protein Tyrosine Phosphatase (IA2) in human serum. They are intended as aids in the diagnosis of autoimmune diabetes mellitus type 1.

DIAGNOSTIC PERFORMANCE		
	ELISA	RIA
Sensitivity	79,3 %	88 %
Specificity	93,8 %	95 %

Medizym® Anti-GAD M /

CentAK® anti-GAD65 M

The Medizym® anti-GAD M and CentAK® anti-GAD65 M are quantitative immunoassays for detecting antibodies against glutamic acid decarboxylase (GAD65) in human serum, aiding in the diagnosis of type 1 diabetes.

DIAGNOSTIC PERFORMANCE		
	ELISA	RIA
Sensitivity	90.5 %	86,2 %
Specificity	94.7 %	92,7 %

Medizym® IAA / CentAK® IAA M

The Medizym® IAA and CentAK® IAA M are quantitative immunoassays based on the use of recombinant human insulin (IAA) to detect antibodies against insulin in human serum, aiding in the diagnosis of type 1 diabetes.

DIAGNOSTIC PERFORMANCE		
	ELISA	RIA
Sensitivity	77.0 %	> 99 %
Specificity	94.0 %	> 99%



Type 1 Diabetes Assays

Enzyme immunoassays for the qualitative and quantitative determination of IgG antibodies against Islet Cell (ICA), Glutamate Decarboxylase (GAD₆₅), Tyrosine Phosphatase (IA2) and Insulin (IAA) in human serum.

HIGH QUALITY – MADE IN GERMANY

- Quality assured handling in routine laboratories
- Incubation at room temperature
- Color- and barcoded reagents (mostly ready-to-use)
- Quantitative results expressed in U/mL
- Excellent diagnostic sensitivity and specificity
- High precision within the measurement range
- CE marked
- Automatable

Contact

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Order Information

Classical IFA	REF	Automated IFA	REF
ICA IFA	85848	AKLIDES® ICA	4129

ELISA	REF	RIA	REF
Medizym® anti-IA ₂ M	3506	CentAK® anti-IA2 M	2050; 2150
Medizym® anti-GAD M	3507	CentAK® anti-GAD65	2070; 2071
Medizym® IAA	3806	CentAK® IAA M	2035