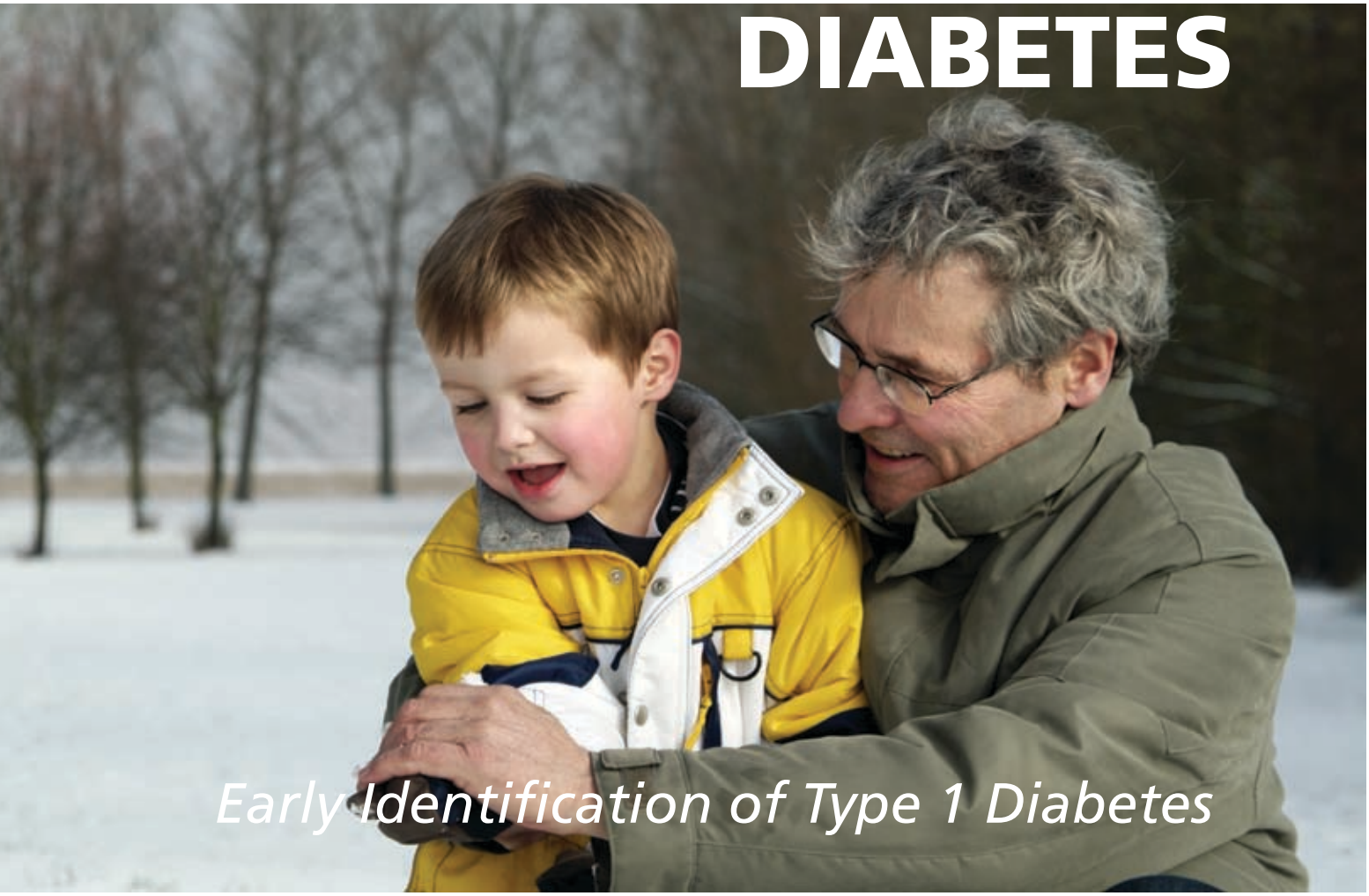
Isletest™-GAD
Isletest™-ICA
Isletest™-IAA



Diabetes: Prediction of Type 1 Diabetes and Identification of Latent Autoimmune diabetes

Comprehensive assay range:

- Isletest-GAD: Glutamic Acid Decarboxylase (GAD) Autoantibodies
- Isletest-ICA: Islet Cell Autoantibodies (ICA)
- Isletest-IAA: Insulin Autoantibodies (IAA)

Unique
The markers of choice for the differential diagnosis and management of Type 1 diabetes

Accurate
High correlation to confirmed clinical samples

Simple
Microwell Enzyme based assay (ELISA)

Convenient
Ready to use reagents
Rapid turnaround

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INTENDED USE

Measurement of autoantibodies to Glutamic Acid Decarboxylase (GAD), Islet Cell and Insulin to aid in the diagnosis and management of the autoimmune progression of diabetes.

Isletest™-GAD is intended for the in vitro quantitative determination of glutamic acid decarboxylase (GAD) autoantibody levels in human serum.

Isletest™-ICA is intended for the in vitro qualitative determination of islet cell autoantibody (ICA) levels in human serum.

Isletest™-IAA is intended for the in vitro qualitative determination of insulin autoantibody (IAA) levels in human serum.

BACKGROUND

The presence of Glutamic Acid Decarboxylase (GAD) Autoantibodies, Islet Cell Autoantibodies (ICA) and Insulin Autoantibodies (IAA) serve as markers for the early diagnosis (up to 7 years before the clinical onset) of Type 1 diabetes. Studies indicate that up to 10% of adult patients initially diagnosed as type 2 diabetics are eventually diagnosed as type 1. In one study, 93% of the subjects tested positive for at least one of the three autoantibodies, and 78% were positive for two or more.

Glutamic Acid Decarboxylase (GAD) Autoantibodies
Antibodies to GAD have been found in 70-90% of Type 1 juvenile diabetics and adult onset diabetics, and have been shown to be the most sensitive marker for identifying persons at risk of developing Type 1 diabetes. Autoantibodies to GAD are generally more prevalent in older children and late-onset Type 1 diabetics, and in some patients, have been detected as early as seven years prior to the onset of clinical disease.

Islet Cell Autoantibodies (ICA)
There are at least four different types of cells located in islets, including alpha cells which secrete glucogon, beta cells (islets of langerhans) which are most abundant and secrete insulin, delta cells which secrete somatostatin, and PP cells which secrete pancreatic polypeptide. There are a large number of autoantigens made up of various combinations of these cells to which autoantibodies may form. Thus a cocktail of these autoantibodies may form and include autoantibodies to GAD as described above. In various studies, ICA have been found in 70-80% of new-onset patients younger than 30 years of age. Among patients with IDDM, the prevalence of ICA decreases with increasing duration of the overt disease. The presence of ICA in nondiabetic relatives has been shown to indicate increased risk for the disease.

Insulin Autoantibodies (IAA)
The presence of autoantibodies to insulin (IAA) is evidence of ongoing destruction of beta cells. IAA are found predominantly, though not exclusively, in young children developing Type 1 diabetes as an early predictive marker. In untreated patients, the prevalence of IAA is almost 100% in young individuals, and almost absent in patients with adult onset Type 1 diabetes. Studies have shown that IAA's may be present in up to 50% of patients with new-onset diabetes.

PERFORMANCE

	Assay Time:	Intra-Assay	Inter-Assay
GAD:	2 hrs. 45 minutes	5.1%CV	4.6%CV
ICA:	2 hrs. 45 minutes	5.6%CV	6.5%CV
IAA:	overnight	9.6%CV	11.7%CV

ORDERING

Catalog No.	Description	
7009	Isletest-GAD ELISA kit -	Quantitative (96 tests)
7010	Isletest-ICA ELISA kit -	Qualitative (96 tests)
7011	Isletest-IAA ELISA kit -	Qualitative (96 tests)

CE and EN ISO 13485:2003 Compliant, Multi-language inserts available

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