Autoantibody Assays for Type 1 Diabetes Mellitus

Quantitative determination of autoantibodies to islet cell antigens and to insulin to aid the diagnosis of type 1 diabetes mellitus (T1DM)

Markers

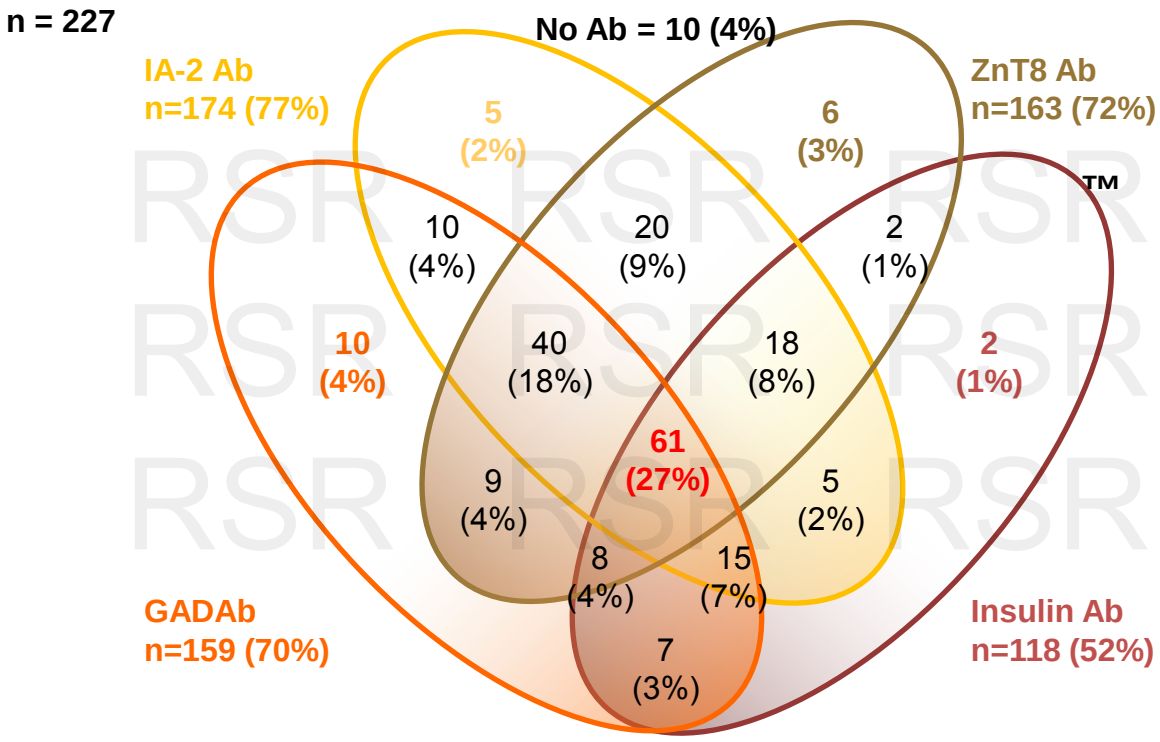
of type 1 diabetes mellitus

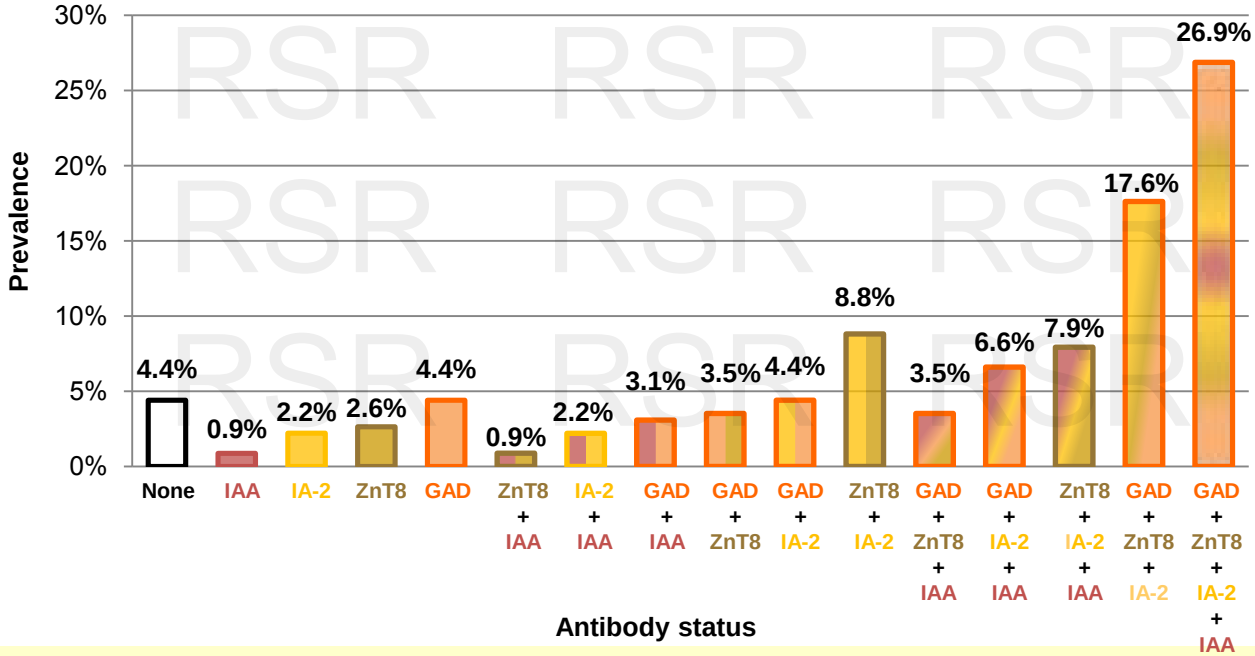
(T1DM) from RSR

ElisaRSR™GADAb
ElisaRSR™IA-2 Ab version2
ElisaRSR™2 Screen ICA™
ElisaRSR™ZnT8 Ab™
ElisaRSR™3 Screen ICA™ New

RiaRSR™GADAb
RiaRSR™IA-2 Ab
RiaRSR™IAA

Overlapping prevalence of antibodies to ZnT8, GAD65, IA-2 and Insulin





227 samples from newly diagnosed type 1 DM patients were tested for ZnT8 Ab, GADAb, IA-2 Ab and Insulin Ab.
RESULTS:
A total of 217 (96%) type 1 DM patients were positive in one or more of the four assays.

Data from L Petruzelkova et al, Diabet Med 2014 **31**: 165-71

Clinical Info

Product Info

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ElisaRSR™GADAb RiaRSR™GADAb
ElisaRSR™IA-2 Ab version2 RiaRSR™IA-2 Ab
ElisaRSR™2 Screen ICA™
ElisaRSR™ZnT8 Ab™ RiaRSR™IAA
ElisaRSR™3 Screen ICA™ New

T1DM

What is T1DM

Definition
Diabetes mellitus is a disorder characterized by hyperglycemia in both fasting and post-prandial states.

Classification of diabetes
Diabetes is classified into four clinical types: type 1 diabetes (T1DM), type 2 diabetes (T2DM), other specific types of diabetes and gestational diabetes (GDM). T1DM includes classical type 1 diabetes in the young and latent autoimmune diabetes in adults (LADA).

Pathogenesis of T1DM
T1DM results from cell-mediated autoimmune destruction of the of pancreatic β-cells, leading to insulin deficiency. It usually occurs in childhood and adolescence, but can occur at any age. However, clinical presentation of T1DM and T2DM may vary; for example, T2DM may present with ketoacidosis, whereas T1DM may have a late onset and slow progression.

Autoantibodies in T1DM
Autoantibodies are not thought to play a direct pathological role in β-cell destruction, but they are important markers of pancreatic autoimmunity. Autoantibodies to four major islet proteins have been identified and serve as diagnostic markers for T1DM; (1) insulin, (2) glutamic acid decarboxylase 65 (GAD65), (3) insulinoma antigen 2 (IA-2, a tyrosine phosphatase) and (4) zinc transporter 8 (ZnT8).

Importance of measuring islet autoantibodies

- Aid in the classification and diagnosis of diabetes
- Identify LADA patients at increased risk for requiring insulin treatment
- Screening organ donors for islet transplantation
- Prediction of T1DM in first degree relatives and in the general population
- Trials for prevention of T1DM
- Assessment of patients with other autoimmune diseases for islet cell autoimmunity

Results of IASP and DASP

The performance of RSR's Kits in the Islet Antibody Standardization Program (IASP) and in the Diabetes Autoantibody Standardization Program (DASP) is summarised below.

RSR Kit	Method	Sensitivity	Specificity	Data from
ElisaRSR™ GADAb	ELISA	86%	98%	IASP2015
RiaRSR™ GADAb	RIA	78%	94%	
ElisaRSR™ IA-2 Ab version2	ELISA	68%	100%	
RiaRSR™ IA-2 Ab	RIA	72%	98%	
ElisaRSR™ 2 Screen ICA™	ELISA	92%	99%	
ElisaRSR™ ZnT8 Ab™	ELISA	76%	97%	
New ElisaRSR™ 3 Screen ICA ™	ELISA	94%	96%	
RiaRSR™ IAA	RIA	32%	99%	DASP2009

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