MAYO CLINIC LABORATORIES

Test Definition: IA2

Islet Antigen 2 (IA-2) Antibody, Serum

Overview

Useful For

Clinical distinction of type 1 from type 2 diabetes mellitus

Identification of individuals at risk of type 1 diabetes (including high-risk relatives of patients with diabetes)

Prediction of future need for insulin treatment in adult-onset diabetic patients

Method Name

Radioimmunoassay (RIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Islet cell antigen 2 (IA2) testing is available individually (this test) and with glutamic acid decarboxylase 65-kilodalton isoform (GAD65), insulin, and zinc transporter 8 (ZnT8) antibodies as a part of DBS1 / Diabetes Mellitus Type 1 Evaluation, Serum. The evaluation is most appropriate to order in the following clinical contexts:

-Distinguishing type 1 (autoimmune) diabetes mellitus from type 2 diabetes mellitus
-Identifying individuals at risk of type 1 diabetes (including high-risk relatives of patients with diabetes)
-Predicting future insulin requirement treatment in patients with adult-onset diabetes

Individual antibody testing would be more appropriate if 1, 2, or 3 of the analytes (GAD65, IA-2, insulin, ZnT8 antibodies) have already been tested and reported negative, and the provider wishes to test for the balance of remaining untested analytes only.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Ambient	72 hours	
	Refrigerated (preferred)	28 days	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Islet cell autoantibodies have been known to be associated with type 1 diabetes mellitus for many years. In recent years, several autoantigens against which islet antibodies are directed have been identified. These include the tyrosine phosphatase-related islet antigen 2 (IA-2), glutamic acid decarboxylase 65 (GAD65), zinc transporter 8 (ZnT8), and insulin. One or more of these autoantibodies are detected in 96% of patients with type 1 diabetes and are detectable before clinical onset, as well as in symptomatic individuals. A serological study of 50 individuals with type 1 diabetes and 50 control subjects conducted simultaneously across 43 laboratories in 16 countries demonstrated a median sensitivity of 57% and a median specificity of 99% for IA-2 antibody in type 1 diabetes. Prospective studies in relatives of patients with type 1 diabetes have shown that development of 1 or more islet autoantibodies (including IA-2 antibody) provides an early marker of progression to type 1 diabetes. Autoantibody profiles identifying patients destined to develop type 1 diabetes are usually detectable before age 3 years. In one study of relatives seropositive for IA-2 antibody, the risk of developing type 1 diabetes within 5 years was 65.3%. Some patients with type 1 diabetes are initially diagnosed as having type 2 diabetes because of symptom onset in adulthood, societal obesity, and initial insulin-independence. These patients with "latent autoimmune diabetes in adulthood" may be distinguished from those patients with type 2 diabetes by detection of 1 or more islet autoantibodies (including IA-2).

Reference Values

< or =0.02 nmol/L

Reference values apply to all ages.

Interpretation

Seropositivity for islet antigen 2 autoantibody (> 0.02 nmol/L) is supportive of:

-A diagnosis of type 1 diabetes

-A high risk for future development of diabetes

-A current or future need for insulin therapy in patients with diabetes

Cautions

Negative results do not exclude the diagnosis of or future risk for type 1 diabetes mellitus. The risk of developing type 1 diabetes may be stratified further by testing for antibodies targeting insulin, glutamic acid decarboxylase, and zinc transporter 8 (ZnT8) and human leukocyte antigen genetic markers. Careful monitoring of hyperglycemia is the mainstay of determining the requirement for insulin therapy.

Clinical Reference

1. Shields BM, Shepherd M, Hudson M, et al. Population-based assessment of a biomarker-based screening pathway to aid diagnosis of monogenic diabetes in young-onset patients. Diabetes Care. 2017;40(8):1017-1025. doi:10.2337/dc17-0224
2. Bingley PJ. Clinical applications of diabetes antibody testing. J Clin Endocrinol Metab. 2010;95(1):25-33
3. Bingley PJ, Bonifacio E, Mueller PW. Diabetes Antibody Standardization Program: first assay proficiency evaluation. Diabetes 2003;52(5):1128-1136
4. Christie MR, Roll U, Payton MA, et al. Validity of screening for individuals at risk for type I diabetes by combined analysis of antibodies to recombinant proteins. Diabetes Care. 1997;20(6):965-970
5. Lampasona V, Petrone A, Tiberti C, et al: Zinc transporter 8 antibodies complement GAD and IA-2 antibodies in the identification and characterization of adult-onset autoimmune diabetes: Non insulin requiring autoimmune diabetes (NIRAD) 4. Diabetes Care. 2010;33(1):104-108

Performance

Method Description

(125)I-labeled recombinant human IA-2 is incubated with patient sample. Anti-human IgG is then added to form an immunoprecipitate. After washing the immunoprecipitate, the amount of (125)I-labeled antigen in the immunoprecipitate is measured using a gamma-counter. The amount of gamma emission in the precipitate is proportional to the amount of IA2-IgG in the sample. Results are reported as units of precipitated antigen (nMol) per L of patient sample.(Masuda M, Powell M, Chen S, et al: Autoantibodies to IA-2 in insulin-dependent diabetes mellitus. Measurements with a new immunoprecipitation assay. Clin Chim Acta 2000;291:53-66)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

3 to 9 days

Specimen Retention Time

28 days

Performing Laboratory Location

Rochester

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

86341

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
IA2	IA-2 Ab, S	81155-4

Result ID	Test Result Name	Result LOINC® Value
89588	IA-2 Ab, S	81155-4