

Overview

**Method Name**  
Enzyme-linked Immunosorbent Assay (ELISA)

**NY State Available**  
No

Specimen

**Specimen Type**  
Serum

**Specimen Required**  
**Collection Container/Tube:**  
**Preferred:** Serum gel  
**Acceptable:** Red top  
**Submission Container/tube:** Plastic vial  
**Specimen Volume:** 1 mL  
**Collection Instructions:**  
1. With 24 hours of collection, centrifuge and aliquot 1 mL of serum into a plastic vial.  
2. Freeze immediately after separation and send frozen.

**Specimen Minimum Volume**  
0.5 mL (Note: Minimum volume does not allow for repeat analysis)

**Reject Due To**

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	107 days	
	Ambient	72 hours	
	Refrigerated	72 hours	

Clinical & Interpretive

**Clinical Information**  
Type 1 diabetes, commonly referred to as insulin-dependent diabetes mellitus (IDDM), is caused by pancreatic beta-cell

destruction that leads to an absolute insulin deficiency.(1) The clinical onset of diabetes does not occur until 80% to 90% of these cells have been destroyed. Prior to clinical onset, type 1 diabetes is often characterized by circulating autoantibodies against a variety of islet cell antigens, including glutamic acid decarboxylase (GAD), tyrosine phosphatase (IA2), and insulin.(2-7) The autoimmune destruction of the insulin-producing pancreatic beta cells is thought to be the primary cause of type 1 diabetes. The presence of these autoantibodies provides early evidence of autoimmune disease activity, and their measurement can be useful in assisting the physician with the prediction, diagnosis, and management of patients with diabetes. Autoantibodies to IA2, a tyrosine phosphatase-like protein, are found in 50% to 75% of type 1 diabetics at and prior to disease onset. These autoantibodies are generally more prevalent in younger onset patients. Because the risk of diabetes is increased with the presence of each additional autoantibody, the positive predictive value of the IA2 antibody test is enhanced when measured in conjunction with antibodies to GAD and insulin.

**Reference Values**

Negative: &lt;7.5 U/mL

Positive: &gt; or = 7.5 U/mL

**Clinical Reference**

1. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care. 1997;20(7):1183-1197
2. Bonifacio E, Bingley PJ. Islet autoantibodies and their use in predicting insulin-dependent diabetes. Acta Diabetol. 1997; 34(3):185-193
3. Verge CF, Gianani R, Kawasaki E, et al. Prediction of type I diabetes in first-degree relatives using a combination of insulin, GAD, and ICA512bdc/IA-2 autoantibodies. Diabetes. 1996; 45(7):926-933
4. Bingley PJ, Bonifacio E, Williams AJ, Genovese S, Bottazzo GF, Gale EA. Prediction of IDDM in the general population: Strategies based on combinations of autoantibody markers. Diabetes. 1997;46(11):1701-1710
5. Pietropaolo M, Hutton JC, Eisenbarth GS. Protein tyrosine phosphatase-like proteins: link with IDDM. Diabetes Care. 1997;20(2):208-214
6. Pietropaolo M, Peakman M, Pietropaolo SL, et al. Combined analysis of GAD65 and ICA512(IA-2) autoantibodies in organ and non-organ-specific autoimmune diseases confers high specificity for insulin-dependent diabetes mellitus. J Autoimmun. 1998;11(1):1-10
7. Borg H, Fernlund P, Sundkvist G. Protein tyrosine phosphatase-like protein IA2-antibodies plus glutamic acid decarboxylase 65 antibodies (GADA) indicates autoimmunity as frequently as islet cell antibodies assay in children with recently diagnosed diabetes mellitus. Clin Chem. 1997;43(12):2358-236

**Performance****PDF Report**

No

**Day(s) Performed**

Varies

**Report Available**

7 to 14 days

Performing Laboratory Location

Esoterix Endocrinology

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](#).

CPT Code Information

86341

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FIAAB	IA-2 Autoantibodies	31209-0

Result ID	Test Result Name	Result LOINC® Value
FIAAB	IA-2 Autoantibodies	31209-0