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MAYO CLINIC LABORATORIES

Test Definition: FDAIP

Diabetes Autoimmune Profile

Overview

Useful For

Diabetes autoantibodies assessment is helpful in identifying and managing patients at risk for development of type 1 diabetes.

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA), Radioimmunoprecipitation

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: 2.5 mL

Collection Instructions:

1. Within 24 hours of collection, centrifuge and aliquot 2.5 mL of serum into a plastic vial.
2. Freeze within 24 hours and send frozen.

Specimen Minimum Volume

1 mL (Note: This volume does **not** allow for repeat testing)

Reject Due To

Gross hemolysis	Reject
Thawing	Cold OK; Warm reject
Lipemia	Reject
EDTA plasma	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container

Serum	Frozen	7 days	

Clinical & Interpretive

Reference Values

Insulin Antibodies
<5.0 uU/mL: Negative
> or =5.0 uU/mL: Positive

Anti GAD 65 Antibodies
<5.0 U/mL: Negative
> or =5.0 U/mL: Positive

IA-2 Autoantibodies
<7.5 U/mL: Negative
> or =7.5 U/mL: Positive

ZNT8 Antibodies
<15 U/mL: Negative
> or =15 U/mL: Positive
Reference ranges apply to all ages.

Interpretation

Published positivity rates for diabetes autoantibodies in new-onset type 1 diabetes patients listed below are based on the combined analysis of GAD-65, ICA 512, insulin antibodies, and ZNT8 antibodies. The combined analysis has a 98% autoimmunity detection rate, with 1.8% of type 1 diabetic individuals remaining as autoantibody-negative.(1)

Positive rate in new-onset type 1 diabetes patients:
GAD-65 antibodies = 68% positive
ICA 512 antibodies = 72% positive
Insulin antibodies = 55% positive
ZnT8 antibodies = 63% positive

An increase in the number of positive antibodies is associated with a higher likelihood of type 1 diabetes.

Less than 3% of type 2 diabetics have positive antibodies.

Clinical Reference

1. Wenzlau JM, Juhl K, Yu L, et al. The cation efflux transporter ZnT8 (Slc30A8) is a major autoantigen in human type 1 diabetes. Proc Natl Acad Sci U S A. 2007;104(43):17040-17045. doi:10.1073/pnas.0705894104

Performance

PDF Report
No

Day(s) Performed
Varies

Report Available
10 to 19 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.

Test Classification
Insulin Antibodies: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

CPT Code Information
86337
86341x3

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FDAIP	Diabetes Autoimmune Profile	Not Provided

Result ID	Test Result Name	Result LOINC® Value
Z6377	Insulin Antibodies	8072-1
Z6378	Anti GAD 65 Antibodies	56540-8
Z6387	IA-2 Autoantibodies	31209-0
Z6388	ZNT8 Antibodies	76651-9
Z6389	Type 1 Diabetes Interpretation	8251-1