

Diabetes Autoimmune Profile

Explanation: The following new orderable, referred to Esoterix Endocrinology, will be available on August 18, 2025.

Test ID: FDAIP

Useful for:

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.

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. (1)

Methods:

Enzyme-linked immunosorbent assay (ELISA), radioimmunoprecipitation

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.

Specimen Requirements:

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/tube: Plastic vial

Specimen Volume: 2.5 mL

Collection Instructions:

1. Centrifuge and aliquot 2.5 mL of serum into a plastic vial.
2. Freeze immediately and send frozen.

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Frozen	7 days

CPT Code:

86337, 86341x3

Day(s) Setup: Varies

Report Available: 10 to 19 days

Questions:

Contact MCS Referrals Supervisors Amy Bluhm or Heather Hilgart at 800-533-1710.