

# **Test Definition: FDAIP**

Diabetes Autoimmune Profile

#### Overview

#### **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)

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

#### **Specimen Minimum Volume**

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



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## **Reject Due To**

Gross	Reject
hemolysis	
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.

#### **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



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## Day(s) Performed

Varies

#### **Report Available**

10 to 19 days

## **Performing Laboratory Location**

**Esoterix Endocrinology** 

#### **Fees & Codes**

#### **Fees**

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

#### **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