

## 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, and those with gestational diabetes)

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

### Highlights

ZnT8 antibody distinguishes type 1 and type 2 diabetes mellitus.

ZnT8 antibody identifies relatives of diabetic patients at most risk for developing diabetes.

ZnT8 antibody predicts the future need for insulin treatment in adult-onset diabetic patients.

ZnT8 antibody predicts the future development of diabetes mellitus in women with gestational diabetes.

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

**Collection Container/Tube:**

**Preferred:** Red top

**Acceptable:** Serum gel

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 2 mL

**Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.

### Specimen Minimum Volume

1 mL

### Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

## Specimen Stability Information

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

## Clinical & Interpretive

### Clinical Information

Islet cell autoantibodies have been known to be associated with type 1 diabetes mellitus since the 1970s.(1) Since 1988, several autoantigens against which islet antibodies are directed have been identified. These include the insulinoma-associated protein 2 (IA-2), glutamic acid decarboxylase 65 (GAD65), insulin, and, most recently, the zinc transporter ZnT8. Only 4% to 7% of patients with type 1 diabetes are autoantibody negative, fewer than 10% have only 1 marker, and around 70% have 3 or 4 markers. These findings have been confirmed in multiple specialty laboratories internationally.

One or more of these autoantibodies are detected in 93% to 96% of patients with type 1 diabetes, both adults and children. These antibodies are also detectable in relatives of type 1 diabetic patients at risk for developing diabetes, before clinical onset. Because of symptom-onset in adulthood, societal obesity, and initial insulin-independence, some patients with type 1 diabetes are initially diagnosed as having type 2 diabetes,. These patients with either "latent autoimmune diabetes in adulthood" or type 1 diabetes mellitus, may be distinguished from those patients with type 2 diabetes by detection of 1 or more islet autoantibodies, including ZnT8 antibody.(2-5) Patients with gestational diabetes can also be stratified for future diabetes risk by detection of 1 or more islet autoantibodies (including ZnT8 antibody).

### Reference Values

<15.0 U/mL

### Interpretation

Seropositivity for ZnT8 autoantibody (> or =15 IU/mL) 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: 1) antibodies targeting insulin, IA2, and GAD65 and 2) HLA genetic markers. Careful monitoring of hyperglycemia is the mainstay of determining the requirement for insulin therapy

## Clinical Reference

1. Bingley PJ: Clinical applications of diabetes antibody testing. J Clin Endocrinol Metab 2010;95:25-33
2. Andersson C, Vaziri-Sani F, Delli A, et al: Triple specificity of ZnT8 autoantibodies in relation to HLA and other islet autoantibodies in childhood and adolescent type 1 diabetes. Pediatr Diabetes 2013;14:97-105
3. Dereke J, Nilsson C, Landin-Olsson M, Hillman M: Prevalence of zinc transporter 8 antibodies in gestational diabetes mellitus. Diabet Med 2012;29:e436-439
4. Gorus FK, Balti EV, Vermeulen I, et al: Screening for insulinoma antigen 2 and zinc transporter 8 autoantibodies: a cost-effective and age-independent strategy to identify rapid progressors to clinical onset among relatives of type 1 diabetic patients. Clin Exp Immunol 2013;171:82-90
5. Petruzelkova L, Ananieva-Jordanova R, Vcelakova J, et al: The dynamic changes of zinc transporter 8 autoantibodies in Czech children from the onset of Type 1 diabetes mellitus. Diabet Med 2014;31:165-171

## Performance

### Method Description

Zinc Transporter 8 (ZnT8) antibodies are principally directed against the C terminal domain of ZnT8. The ZnT8 autoantibody ELISA is based on the bridging principle that employs the ability of divalent ZnT8 autoantibodies to bind to ZnT8 coated on to the plate well with one arm, and to liquid ZnT8-biotin with the other arm. Calibrators or undiluted serum samples in duplicate are added to ZnT- coated plate wells and incubated overnight. ZnT8-biotin is added to each well and plate. After another incubation, aspiration, and wash, streptavidin-peroxidase is added to each well. Another incubation, aspiration, and wash are performed and peroxidase substrate is added. After a final incubation, 0.5 mol/L H<sub>2</sub>S<sub>04</sub> stop solution is added to each well. Absorbance is measured at 450 nm, blanked against wells containing peroxidase substrate and H<sub>2</sub>S<sub>04</sub> only.

### PDF Report

No

### Day(s) Performed

Tuesday, Thursday

### Report Available

3 to 7 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.

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- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test 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
EZNT8	ZnT8 Ab, S	76651-9

Result ID	Test Result Name	Result LOINC® Value
64926	ZnT8 Ab, S	76651-9