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)

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

Method Name
Radioimmunoassay (RIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Specimen Volume: 1.5 mL

Specimen Minimum Volume
1 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
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</table>
Clinical and Interpretive

Clinical Information
Islet cell autoantibodies have been known to be associated with type 1 diabetes mellitus for 36 years. In recent years, several autoantigens against which islet antibodies are directed have been identified. These include the tyrosine phosphatase-related islet antigen 2 (IA-2), glutamic acid decarboxylase 65, the zinc transporter ZnT8, and insulin. One or more of these autoantibodies are detected in 96% of patients with type 1 diabetes, and are detectable before clinical onset, as well as in asymptomatic individuals. A serological study of 50 type 1 diabetics and 50 control subjects conducted simultaneously across 43 laboratories in 16 countries demonstrated a median sensitivity of 57% and a median specificity of 99% for IA-2 antibody in type 1 diabetes. Prospective studies in relatives of patients with type 1 diabetes have shown that development of 1 or more islet autoantibodies (including IA-2 antibody) provides an early marker of progression to type 1 diabetes. Autoantibody profiles identifying patients destined to develop type 1 diabetes are usually detectable before age 3. In 1 study of relatives seropositive for IA-2 antibody, the risk of developing type 1 diabetes within 5 years was 65.3%. Some patients with type 1 diabetes are initially diagnosed as having type 2 diabetes because of symptom onset in adulthood, societal obesity, and initial insulin-independence. These patients with "latent autoimmune diabetes in adulthood" may be distinguished from those patients with type 2 diabetes by detection of 1 or more islet autoantibodies (including IA-2).

Reference Values
< or =0.02 nmol/L

Reference values apply to all ages.

Interpretation
Seropositivity for IA-2 autoantibody (> 0.02 nmol/L) 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, glutamic acid decarboxylase, and zinc transporter 8 (ZnT8) and 2) HLA genetic markers. Careful monitoring of hyperglycemia is the mainstay of determining the requirement for insulin therapy.

Supportive Data
See clinical information and references.

Clinical Reference

**Performance**

**Method Description**

(125) I-labeled recombinant human IA-2 is added to the test serum; if antibody is present, it forms a soluble complex with the (125) I-labeled IA-2. Subsequent addition of goat antihuman IgG and IgM precipitates the complex. The amount of radioactivity in the precipitate is proportional to the level of antibody in the serum.(Masuda M, Powell M, Chen S, et al: Autoantibodies to IA-2 in insulin-dependent diabetes mellitus. Measurements with a new immunoprecipitation assay. Clinica Chimica Acta 2000;291:53-66)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Tuesday, Friday; 10 p.m.

**Analytic Time**

3 days/negative, 5 days/positive

**Maximum Laboratory Time**

9 days

**Specimen Retention Time**

28 days

**Performing Laboratory Location**

Rochester

**Fees and 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 Regional Manager. For assistance, contact Customer Service.

**Test Classification**

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

**CPT Code Information**

86341

**LOINC® Information**

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<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>81155-4</td>
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<tr>
<td>Result ID</td>
<td>Test Result Name</td>
<td>Result LOINC Value</td>
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