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

Ordering Guidance
Islet cell antigen 2 (IA2) testing is available individually (this test) and with glutamic acid decarboxylase 65-kilodalton isoform (GAD65), insulin, and zinc transporter 8 (ZnT8) antibodies as a part of DBS1 / Diabetes Mellitus Type 1 Evaluation, Serum. The evaluation is most appropriate to order in the following clinical contexts:
- Distinguishing type 1 (autoimmune) diabetes mellitus from type 2 diabetes mellitus
- Identifying individuals at risk of type 1 diabetes (including high-risk relatives of patients with diabetes)
- Predicting future insulin requirement treatment in patients with adult-onset diabetes

Individual antibody testing would be more appropriate if 1, 2, or 3 of the analytes (GAD65, IA-2, insulin, ZnT8 antibodies) have already been tested and reported negative, and the provider wishes to test for the balance of remaining untested analytes only.

Specimen Required
Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Specimen Volume: 1.5 mL

Specimen Minimum Volume
1 mL

Reject Due To
**Test Definition: IA2**

**Islet Antigen 2 (IA-2) Antibody, Serum**

### Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</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>
<td></td>
</tr>
</tbody>
</table>

### Clinical & Interpretive

**Clinical Information**

Islet cell autoantibodies have been known to be associated with type 1 diabetes mellitus for many 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, zinc transporter 8, 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 symptomatic individuals. A serological study of 50 individuals with type 1 diabetes 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 one 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 islet antigen 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 antibodies targeting insulin, glutamic acid decarboxylase, and zinc transporter 8 (ZnT8) and human leukocyte antigen genetic markers. Careful monitoring of hyperglycemia is the mainstay of determining the requirement for insulin therapy.
Clinical Reference

Method Description
Iodine-125 ([125]I)-labeled recombinant human islet cell antigen (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 precipitates the complex. The amount of radioactivity in the precipitate is proportional to the level of antibody in the serum. (Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
3 to 9 days

Specimen Retention Time
28 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.
Test Definition: IA2
Islet Antigen 2 (IA-2) Antibody, Serum

- 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 US Food and Drug Administration.

CPT Code Information
86341

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC® Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA2</td>
<td>IA-2 Ab, S</td>
<td>81155-4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC® Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>89588</td>
<td>IA-2 Ab, S</td>
<td>81155-4</td>
</tr>
</tbody>
</table>