

Provincial Laboratory Services



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Health PEI
One Island Health System

Diabetes Antibody Testing

March 30, 2022

This information applies to: *Island Physicians and Nurse Practitioners*

The presence of islet cell autoantibodies are known to be associated with type 1 diabetes mellitus (T1DM). In recent years, the specific islet autoantigens have been identified and include the tyrosine phosphatase-related islet antigen 2 (IA-2), glutamic acid decarboxylase 65 (GAD 65), zinc transporter 8 (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 symptomatic individuals. Testing for “Islet Cell Antibodies” represents an older methodology using immunofluorescence that is less specific for T1DM than the aforementioned islet antigens. Do not order Islet cell antibodies.

Testing for anti-GAD-65, anti-ZnT8, anti-IA2, and anti-Insulin antibodies are now available as “Diabetes Antibody Panel”. Inpatient testing is requested through Cerner and outpatient requests should be written on the bottom of a laboratory requisition. Collect in 6 mL Red Top tube filled completely as the test requires at least 3 mL of serum. Grossly lipemic, hemolytic, icteric samples will be rejected. Fasting specimens are recommended for patients with hypertriglyceridemia.

Search: Contains: Type:

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<input type="checkbox"/> ANES PROTOCOL Diabetes Management (Day Surg...
<input type="checkbox"/> Diabetes Antibody Panel
<input type="checkbox"/> Diabetes mellitus Type I Evaluation
<input type="checkbox"/> Diabetes Supply Prescription (For In-Patient Education)

Who to order on?

1. New suspected T1DM
2. New DKA to differentiate from other types of ketoacidosis- e.g. euglycemic DKA, ketosis prone T2DM
3. Diagnostic uncertainty versus atypical T2DM e.g. thin type 2, LADA, MODY

Sample Reports

Testing is performed at Mayo Clinic where it is reported as **Diabetes Mellitus T1 Evaluation**. On PEI the test is ordered as **Diabetes Antibody Panel**, which makes more sense clinically. See next page for sample reports. Low positive titre of a single antibody does not establish a diagnosis of type 1 DM.

ORDERED: Diab.Mel.T1 Ev.
 COMMENTS: External reference nu
 ACT WKST: MAYO 13/12/21 #1

Test	Result	Flag	Reference
Diab.Mel.T1 Ev.			
GAD 65 AB	0.07	H	<=0.02 nmol/L
Insulin AB	0.13	H	<=0.02 nmol/L
Zinc Transf AB	204.0	H	<=15.0 U/mL
Islet Ag2 AB	0.00		<=0.02 nmol/L
DBS1 Interpreta	See below		
<p>- When found in isolation, the sensitivities of these autoantibodies for type 1 diabetes are 74% (GAD65 antibody), 75% (IA-2) antibody, 69% (insulin antibody) and 69% (ZnT8). When all 4 antibodies are tested for, and at least 1 autoantibody is detected, the combined sensitivity for type 1 diabetes is 98%, with a specificity of 99-100%.</p> <p>- These autoantibodies may also be detectable before the clinical onset of diabetes. The cumulative risk of a seropositive patient developing diabetes is 17% for 1 autoantibody, 39% for 2 antibodies, 70% for 3 antibodies and 80% for 4 antibodies.</p> <p>Test is performed at Mayo Medical Laboratories.</p>			

Test	Result	Flag	Reference
Diab.Mel.T1 Ev.			
GAD 65 AB	1.49	H	<=0.02 nmol/L
Insulin AB	0.00		<=0.02 nmol/L
Zinc Transf AB	> 500.0	H	<=15.0 U/mL
Islet Ag2 AB	1.00	H	<=0.02 nmol/L
DBS1 Interpreta	See below		
<p>This profile is consistent with a diagnosis of type 1 diabetes mellitus.</p> <p>- When found in isolation, the sensitivities of these autoantibodies for type 1 diabetes are 74% (GAD65 antibody), 75% (IA-2) antibody, 69% (insulin antibody) and 69% (ZnT8). When all 4 antibodies are tested for, and at least 1 autoantibody is detected, the combined sensitivity for type 1 diabetes is 98%, with a specificity of 99-100%.</p> <p>- These autoantibodies may also be detectable before the clinical onset of diabetes. The cumulative risk of a seropositive patient developing diabetes is 17% for 1 autoantibody, 39% for 2 antibodies, 70% for 3 antibodies, and 80% for 4 antibodies.</p> <p>Test is performed at Mayo Medical Laboratories.</p>			

Other testing considerations:

1. If a firm diagnosis of T1DM has not been previously established, consider measuring a C-peptide level after 3-5 years of T1DM as level should be low. Other conditions that can be associated with insulin deficiency including pancreatitis related DM, pancreatectomy, immunotherapy related diabetes.
2. Specific autoantibodies are present in conditions besides T1DM, e.g. anti-GAD65 in some neurological conditions and anti-insulin. These tests remain available as standalone tests for non-T1DM conditions. ZnT8 and IA-2 are only available as part of the panel.
3. Insulin antibodies can be present in individuals on long term insulin therapy (but abnormal when present at diagnosis) and in severe insulin resistance.
4. The turnaround time for this test is at least 1 week and testing should be performed among clinically stable patients. This ensures the most optimal specimen and limits iatrogenic anemia in acute presentations of DKA.
5. Test available once per patient lifetime. Repeat testing only available with Clinical Chemist approval.

For more information, contact:

FOR MORE INFORMATION PLEASE DO NOT HESITATE TO CONTACT:

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