Clinical Use
• Assess risk of type 1 diabetes
• Predict onset of type 1 diabetes
• Diagnose new onset type 1 diabetes

Reference Range
≤1 U/mL

Interpretive Information
• Type 1 diabetic patients
• Patients at risk for developing type 1 diabetes
• Stiff-man syndrome (SMS)

Clinical Background
Type 1 diabetes mellitus is characterized by lymphocytic infiltration of islet cells and circulating autoantibodies against a variety of islet cell antigens (ICA). These include glutamic acid decarboxylase (GAD), insulin, IA-2, GM2-1, and others. Direct assays for autoantibodies to GAD-65, IA-2, and insulin are now available for detecting individuals with a genetic predisposition to type 1 diabetes.

GAD-65 autoantibodies are observed in 70% to 80% of prediabetic and type 1 diabetic subjects including 7% to 8% of adult onset diabetics with type 1 diabetes. When a positive GAD-65 antibody test is coupled with positive autoantibody tests for IA-2 and insulin, the risk of diabetes increases to >90% (see Test Application and Interpretation section).

Method
• Radiobinding assay
• Analytical sensitivity: 0.2 U/mL

Specimen Requirements
1 mL frozen serum
0.2 mL minimum

No additive red top preferred
SST red top acceptable