Lab Dept: Serology
Test Name: GLUTAMIC ACID DECARBOXYLASE ANTIBODY

General Information

Lab Order Codes: GAD

Synonyms: GAD65 Islet Cell Antibody; Glutamic Acid Decarboxylase (GAD65) Antibody Assay, Serum; 64K Antibody; Anti-GAD Antibodies; Anti-Glutamic Acid Decarboxylase Ab; Beta Cell Antibody; GAD65 Antibody; Glutamic Decarboxylase Antibodies; Islet Cell Antibody; Stiffman Syndrome

CPT Codes: 83519 – Immunoassay for analyte other than infectious agent antibody or infectious agent antigen, quantitative by radioimmunoassay

Test Includes: GAD65 level reported in U/mL.

Logistics

Test Indications: Islet cell antibodies are associated with autoimmune endocrine disorders including insulin dependant diabetes mellitus.

Lab Testing Sections: Serology - Sendouts

Referred to: Esoterix, Inc. (ESL Test: 500236)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 3 – 8 days, performed Monday and Wednesday

Special Instructions: N/A

Specimen

Specimen Type: Blood

Container: SST (Gold, marble or red) tube

Draw Volume: 1.5 mL (Minimum: 0.3 mL) blood
**Processed Volume:** 0.5 mL (Minimum: 0.1 mL) serum

Note: Minimum volume does not allow for repeat analysis.

**Collection:** Routine blood collection

**Special Processing:** Lab Staff: Centrifuge specimen, remove serum aliquot into a screw-capped round bottom plastic vial within 1 hour of collection. Store and ship at frozen temperatures. Forward promptly.

**Patient Preparation:** None

**Sample Rejection:** Mislabeled or unlabeled specimens

---

### Interpretive

**Reference Range:**

- <0.5 U/mL = Negative
- >= 0.5 U/mL = Positive

**Note:** This test was developed and its performance characteristics determined by Esoterix Endocrinology. It has not been cleared or approved by the US Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes.

**Critical Values:** N/A

**Limitations:** N/A

**Methodology:** Immunoprecipitation Assay

**References:** Esoterix, Inc. February 2018

**Updates:**

3/28/2011: CPT update, previously reported as 86341
2/1/2018: Collection container update.