

Glutamic Acid Decarboxylase Autoantibody (GADAb)

ELISA

ISLET CELL AUTOIMMUNITY

ASSAY CHARACTERISTICS

Semi-Quantitative

Calibration: 5 Calibrators, 5 - 250 U/mL
NIBSC 97/550

Controls (Included): 1 Positive, 1 Negative

TOTAL RUNNING TIME

2 Hours and 40 Minutes

SPECIMEN MATRIX

Human Serum

REFERENCE RANGE

> 5.0 U/mL: Positive

PRECISION

Intra-Assay		Inter-Assay	
Dose (U/mL)	% CV	Dose (U/mL)	% CV
4.8	4.0	5.7	6.5
7.5	3.1	8.1	10.1
97.2	7.3	96.9	5.7

PATIENT GROUP NUMBER OF PATIENTS POSITIVE FOR GADAB %

Type 1 Diabetes	83/99	83%
Suspected Type 1 Diabetes	36/68	56%
Type 2 Diabetes	3/40	8%
Graves' Disease	0/20	0%
Hashimoto's Thyroiditis	0/10	0%
Rheumatoid Arthritis	0/10	0%
Systemic Lupus Erythematosus	0/10	0%
Healthy Blood Donors	2/120	2%

CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity:	83%
Specificity:	99%

The KRONUS Glutamic Acid Decarboxylase Autoantibody (GADAb) ELISA Assay Kit is for the semi-quantitative determination of glutamic acid decarboxylase antibody in human serum, and is useful as an aid in the diagnosis of Type 1 diabetes mellitus (autoimmune mediated diabetes).

Diabetes mellitus is generally classified as either Type 1 (insulin dependent diabetes mellitus) or Type 2 (non-insulin dependent diabetes mellitus). In most instances, the onset of type 1 diabetes (IDDM) is the result of autoimmune destruction of insulin-producing beta cells in the pancreatic islets and the ensuing loss of endogenous insulin secretion.

Measurement of these immunologic markers has been shown to be of considerable value in assisting the attending clinician with the diagnosis of patients with diabetes.

Glutamic acid decarboxylase (GAD) is a major target of autoantibodies associated with the development of IDDM. Autoantibodies to GAD are present in the majority of patients at the clinical onset of IDDM and can persist for up to 10-20 years after diagnosis.

ORDERING INFORMATION

KR7710 — 96 Well Kit



For In Vitro Diagnostic Use



800.4.KRONUS (800.457.6687) | 208.377.4800 | www.kronus.com | kronus@kronus.com

ASSAY PROCEDURE

Sample Volume: 25 μ L per Well

Calibrators, Controls and Samples into Coated Wells: 25 μ L
1 Hour Incubation with Shaking at Room Temperature
Wash Wells 3 Times

GAD-Biotin: 100 μ L
1 Hour Incubation with Shaking at Room Temperature
Wash Wells 3 Times

SA-POD: 100 μ L
20 Minute Incubation with Shaking at Room Temperature
Wash Wells 3 Times

TMB Substrate: 100 μ L
20 Minute Incubation in the Dark at Room Temperature

Stop Solution: 100 μ L
Read Absorbance at 450 nm

Total Assay Time is Approximately 2 Hours and 40 Minutes

REFERENCES

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4. Bell DSH. Should anti-glutamic acid decarboxylase antibody levels be determined in new-onset diabetes? Endocr Pract. 2000 Mar;6(2):214-216.
5. Baekkeskov S, Aanstoot HJ, Christgau S, et al. Identification of the 64K autoantigen in insulin-dependent diabetes as the GABA-synthesizing enzyme glutamic acid decarboxylase. Nature. 1990 Sep;347(6289):151-156.
6. Powell M, Prentice L, Asawa T, et al. Glutamic acid decarboxylase autoantibody assay using 125I-labelled recombinant GAD65 produced in yeast. Clin Chim Acta. 1996 Dec;256(2):175-188.
7. Ohta M, Obayashi H, Takahashi K, et al. Radioimmunoprecipitation assay for glutamic acid decarboxylase antibodies evaluated clinically with sera from patients with insulin-dependent diabetes mellitus. Clin Chem. 1996 Dec;42(12):1975-1978.
8. Meinck HM, Faber L, Morgenthaler N. et al. Antibodies against glutamic acid decarboxylase: prevalence in neurological diseases. J Neurol Neurosurg Psychiatry. 2001 Jul;71(1):100-103.



...Your Source for Sensitive Autoimmune Diagnostics

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