

Glutamic Acid Decarboxylase (GAD) Related Products (recombinant proteins and autoantibody ELISA kit)

◆ Glutamic acid decarboxylase autoantibodies (GADA) are found in 70% to 80% of individuals with new-onset type 1 diabetes, making it the most frequent autoantibody in autoimmune diabetes. GADA can be detected in serum for many years post diagnosis, and high concentrations of GADA have been considered as a marker of faster β -cell exhaustion in these patients. Furthermore, GADA in non-diabetic individuals predicts the later development of type 1 diabetes¹. Besides autoimmune diabetes, GADA also exists in Stiff Man Syndrome, autoimmune poly-endocrinopathies, and some of Grave's Disease patients².

◆ ImmunoDiagnostics has generated a series of insect cell-derived bioactive recombinant proteins, along with a highly sensitive and specific ELISA kit for precision detection of GAD autoantibody (GADA) titers in human serum (Plasma samples are not recommended).

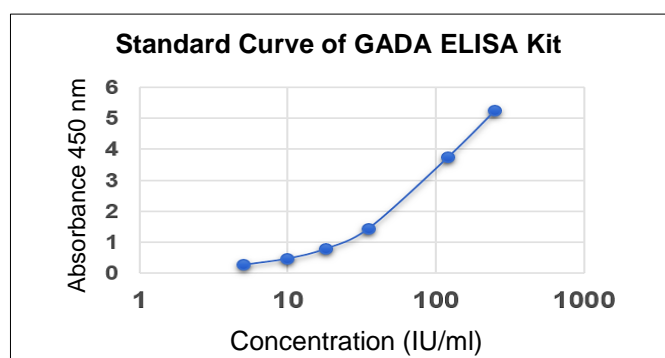
Typical results

(Example only, not for calculation of actual results)

Calibrator*	Concentration (IU/ml)	OD450	OD405
1	2000	7.86	2.3425
2	250	5.24	1.56
3	120	3.732	1.0865
4	35	1.445	0.439
5	18	0.794	0.2565
6	10	0.4785	0.168
7	5	0.276	0.1125
Negative Control	0	0.096	0.0655
Positive Control	15.18	0.746	0.235

Cut off	IU/ml
Negative	< 5 IU/ml
Positive	\geq 5 IU/ml

*Calibrator standardised against NIBSC 97/550.

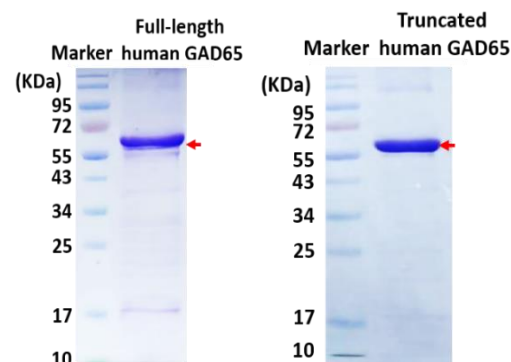


Clinical Evaluation		
Sensitivity	92.5% (n=80)	
Specificity	95% (n=150)	
Inter Assay Precision		
Sample	IU/ml (n=20)	CV
1	120	5.75%
2	18	6.66%
3	5	5.26%
Intra Assay Precision		
Sample	IU/ml (n=20)	CV
1	120	6.61%
2	18	4.63%
3	5	5.65%

This cut off has been validated at ImmunoDiagnostics. However, we recommend each laboratory establish its own reference ranges of GADA levels to distinguish healthy and pathological subjects, as well as include its own internal control samples in the assay.

Bioactive Recombinant Proteins	Expression System	Cat No.
Full-length human GAD65 (flGAD65)	<i>Spodopterafrugiperda</i> Sf9 cell	41842
Truncated human GAD65 (trGAD65)	<i>Spodopterafrugiperda</i> Sf9 cell	41846
Assay Kit	Assay Range	Cat No.
GADA Elisa Kit	0-2000 IU/ml	31840

SDS-PAGE Analysis of Recombinant GAD



References:

1. Liu B, et al. Past, present and future of latent autoimmune diabetes in adults. *Diabetes Metab Res Rev*. 2019 Jul 18:e3205.
2. Björk E, et al. GAD autoantibodies in IDDM, stiff-man syndrome, and autoimmune polyendocrine syndrome type I recognize different epitopes. *Diabetes*. 1994 Jan;43(1):161-5.