

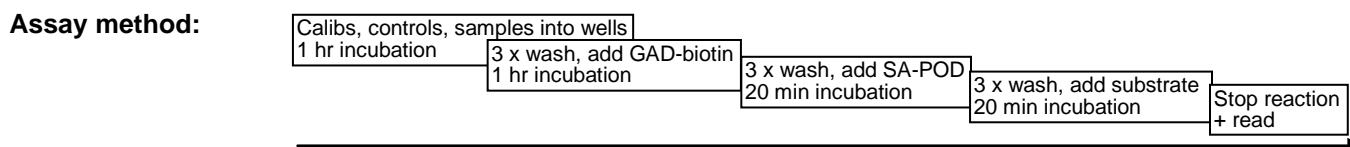
Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD₆₅) in serum

Disease application: Type 1 Diabetes Mellitus (DM)

Test samples: Sera may be used. Do not use lipaemic or haemolysed serum samples. Do not use plasma. No interference was observed with bilirubin at 20 mg/dL, haemoglobin at 500 mg/dL or intralipid up to 3,000 mg/dL.

Sample volume: 25 µL per well

Total assay time: Approx. 3 hours



Sensitivity: 78% n = 50 for type 1 DM patients (IASP 2013)
74% n = 50 for type 1 DM patients (IASP 2012)
90% n = 50 for type 1 DM patients (DASP 2010)

Specificity: 98% n = 90 for healthy blood donors (IASP 2013)
99% n = 90 for healthy blood donors (IASP 2012)
94% n = 90 for healthy blood donors (DASP 2010)

ISAP 2012 type 1 DM group contained 31 sera (out of the total of 50) that had not been included in DASP 2010. All of the sera positive in DASP 2010 that were included in IASP 2012 were also positive in IASP 2012. The reduction in the sensitivity is entirely due to the change in the composition of the group and does not indicate any reduction in the effectiveness of the assay in detection of GAD₆₅ autoantibodies in type 1 DM patients' sera. RSR's results with the ElisaRSR™ GADAb kit gave excellent comparative performance characteristics for both specificity and sensitivity in the IASP 2012 GADA workshop. 4 other users of the RSR GADAb ELISA kits also had excellent results in the workshop.

Parameter	Sensitivity	Specificity	Accuracy
Mean (n=7)	73%	95%	85%
Reported Minimum	64%	82%	76%
Reported Maximum	82%	100%	90%

Abstracted from *Lab reported Sensitivity and Specificity, IASP 2012*. n=7 including the ElisaRSR™ GADAb and other users of the RSR GADAb ELISA kit.

Calibrator range: 5 - 2000 units/mL (standardised with NIBSC 97/550)

Cut-off: Negative: <5 unit/mL; Positive: ≥ 5unit/mL

Lower detection limit: 0.57 units/mL (mean + 2 standard deviations in assay of negative control; n = 20)

Advantages: A non-isotopic method with easy assay format for use in routine clinical laboratories and suitable for automated systems. It offers even higher disease specificity and sensitivity than RiaRSR™ GADAb.

Features: Reliable and convenient method to measure specific GAD antibodies which are a major component of ICA in type 1 DM. GADAb levels in test samples are expressed as NIBSC 97/550 units (www.nibsc.ac.uk). GADAb measurements are useful for diagnosis and prediction of type 1 DM.

Note: For samples with low levels of GADAb, assay with & without RSR unlabelled recombinant GAD in order to check specificity.

Sensitivity and specificity were assessed in Diabetes Antibody Standardization Program (DASP) 2010, Islet Autoantibody Standardization Program (IASP) 2012 and IASP 2013.

RSR participates in the UK NEQAS (national external quality assessment service) scheme.

Kit size: 96 wells

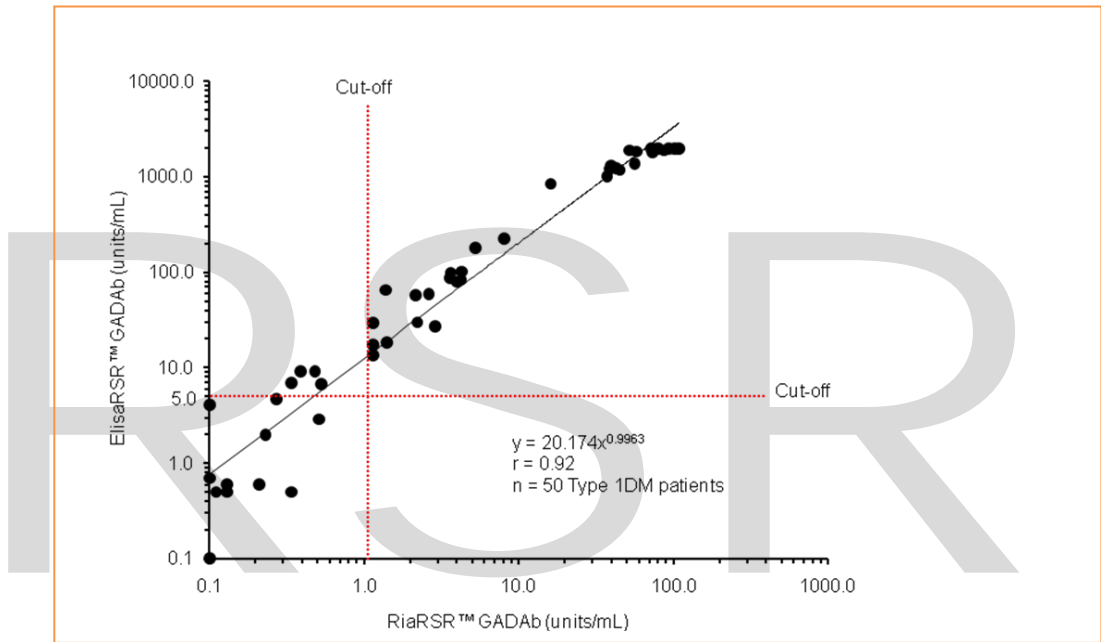
Order code: GDE/96

Literature: H Brooking et al, Clinica Chimica Acta 2003 **331**: 55-59
A sensitive non-isotopic assay for GAD₆₅ autoantibodies
S Chen et al, Clinica Chimica Acta 2005 **357**: 74-83
Sensitive non-isotopic assays for autoantibodies to IA-2 and to a combination of both IA-2 and GAD₆₅

Stiff-person syndrome (SPS): ElisaRSR™ GADAb may be used to detect SPS for research use only. See for example: -
M Hadjivassiliou et al, Acta Neurol Scand 2011 **123**:175-180
GAD antibody-associated neurological illness and its relationship to gluten sensitivity

This kit is intended for in-vitro use by professional persons only. The data quoted is for guidance only. Each laboratory should establish its own normal and pathological reference ranges for the assay and should include its own panel of control samples in the assay along with the controls provided as part of the kit.

Correlation:



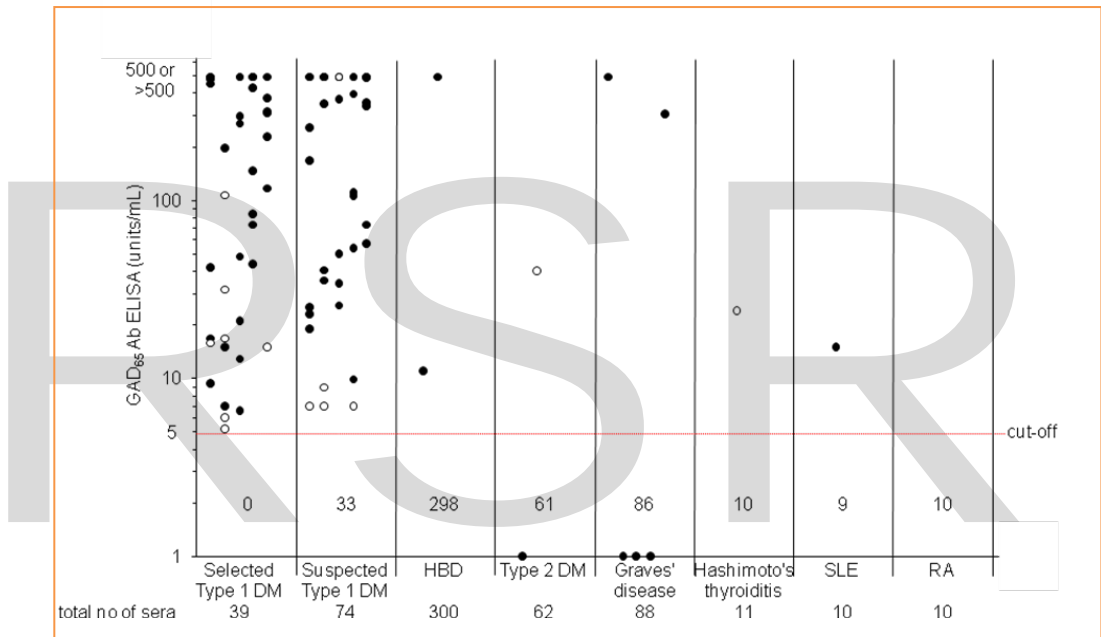
1 unit/mL (RiaRSR™ GADAb) = 25 units/mL (approximately) of NIBSC 97/550 Units/mL (ElisaRSR™ GADAb); standardised with NIBSC 97/550

Comparison:

n=50 type 1 DM patients		RiaRSR™ GADAb	
		Negative	Positive
ElisaRSR™ GADAb	Negative	11	0
	Positive	4	35

Concordance rate: 92.0%

Measurements in different patient groups:



GAD₆₅ Ab levels measured by ELISA in different patient groups. HBD = healthy blood donors, SLE = systemic lupus erythematosus, RA = rheumatoid arthritis. ○ = sera positive in GAD₆₅ Ab ELISA but negative in the ¹²⁵I-GAD₆₅ RIA.

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