

FAST IA-2 AUTOANTIBODY ELISA KIT**ElisaRSR™ Fast IA-2 Ab**

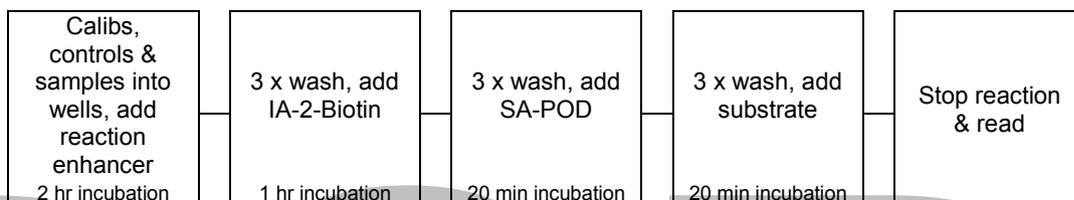
Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to IA-2 in serum

Disease application: Type 1 Diabetes Mellitus (DM)

Test samples: Sera may be used. Do not use lipaemic or haemolysed serum samples.

Sample volume: 50 µL per well

Total assay time: Approx. 4 hours

Assay method:

Sensitivity: 96% n = 50 for type 1 DM patients

Specificity: 100% n = 155 for healthy blood donors

Calibrator range: 7.5 – 4000 u/mL (standardised by NIBSC 97/550)

Cut-off: Negative: <7.5 u/mL; Positive: ≥7.5 u/mL

Limit of detection: 2.74 u/mL (mean + 2 standard deviations in assay of negative control and low analyte sample; n = 20 in 3 kit lots)

Advantages: A quick and easy to use non-isotopic assay suitable for use in routine clinical laboratories in automated or manual formats. Refrigeration not required for incubation steps. Kit offers similar specificity and sensitivity to ElisaRSR™ IA-2 Ab Version 2.

Features: Reliable and convenient method to measure specific IA-2 antibodies which are a major component of ICA in type 1 DM and which are useful for diagnosis and prediction of type 1 DM. Kit calibrators are NIBSC 97/550 units. IA-2 Ab measurements are useful for diagnosis and prediction of type 1 DM.

Kit size: 96 wells

Order code: FKIE/96

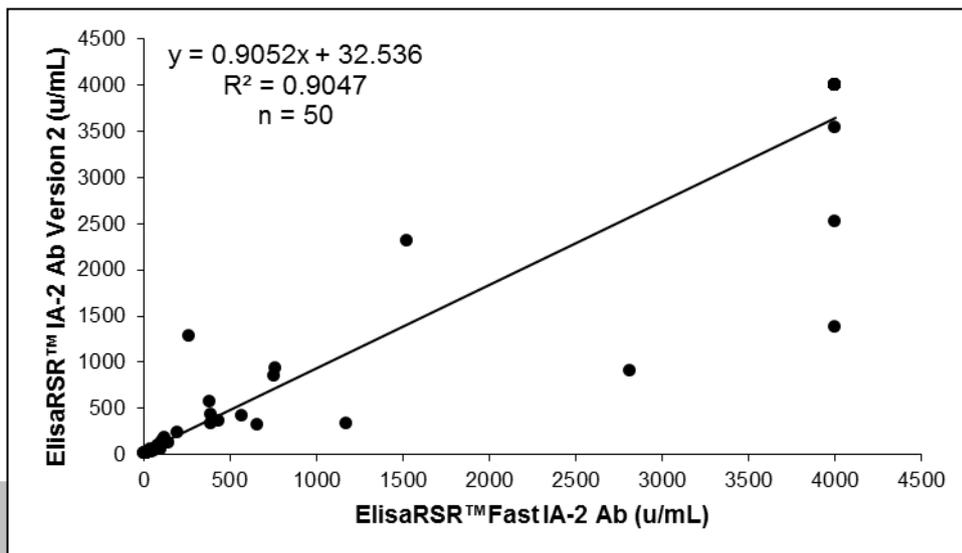
Literature: S Chen et al, Clinica Chimica Acta 2005 **357**: 74 – 83
Sensitive non-isotopic assays for autoantibodies to IA-2 and to a combination of both IA-2 and GAD₆₅

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.

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ElisaRSR™ Fast IA-2 Ab

Correlation:



Comparison:

	ElisaRSR™ IA-2 Ab Version 2	ElisaRSR™ Fast IA-2 Ab	Notes
Total assay time	18 hours	4 hours	
Cut-off	≥7.5 u/mL	≥7.5 u/mL	As per IFU
Assay sensitivity	100% 50/50 positive	96% 48/50 positive	n = 50 Type 1 DM

n = 50 Type 1 DM	ElisaRSR™ IA-2 Ab Version 2	
	Negative	Positive
ElisaRSR™ Fast IA-2 Ab	Negative	0
	Positive	2
	Negative	0
	Positive	48

Concordance rate: 96%