

### FAST 2 SCREEN ISLET CELL AUTOANTIBODY ELISA KIT

#### ElisaRSR™ Fast 2 Screen ICA™

**Description:** Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD<sub>65</sub>) and/or IA-2 in serum

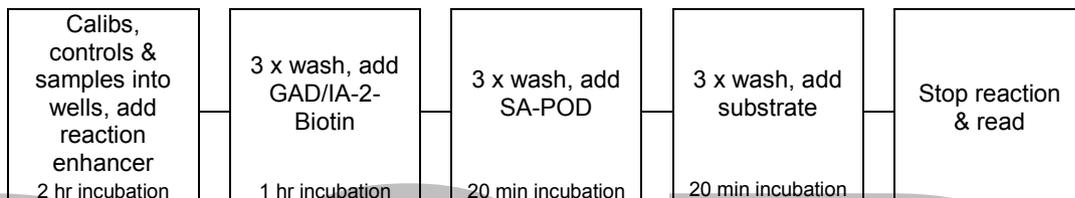
**Disease application:** Type 1 Diabetes Mellitus (DM)

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

**Sample volume:** 50 µL per well

**Total assay time:** Approx. 4 hours

**Assay method:**



**Sensitivity:** 88% n = 50 for type 1 DM patients

**Specificity:** 99% n = 100 for healthy blood donors

**Calibrator range:** 4 – 450 u/mL (standardised by NIBSC 97/550)

**Cut-off:** Negative: <4.0 u/mL; Positive: ≥4.0 u/mL

**Limit of detection:** 0.68 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.

**Features:** Reliable and convenient method to measure specific GAD and/or 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.

**Kit size:** 96 wells

**Order code:** FGIE/96

**Literature:** H Brooking et al, Clinica Chimica Acta 2003 **331**: 55 – 59  
A sensitive non-isotopic assay for GAD<sub>65</sub> autoantibodies

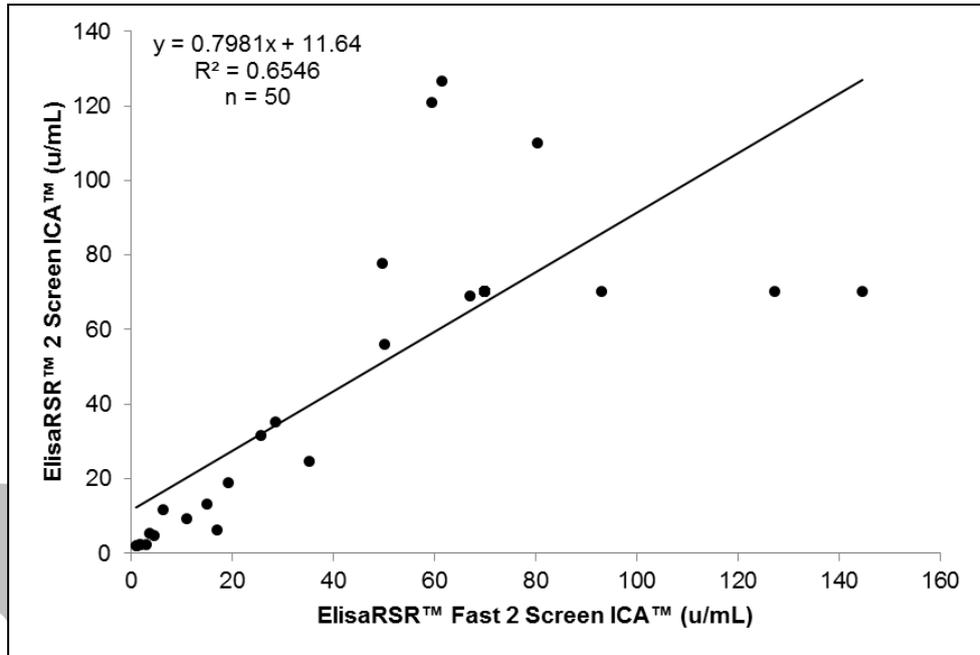
S Chen et al, Clinica Chimica Acta 2005 **357**: 74 – 83  
Sensitive non-isotopic assays for autoantibodies to IA-2 and to a combination of both IA-2 and GAD<sub>65</sub>

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.

### FAST 2 SCREEN ISLET CELL AUTOANTIBODY ELISA KIT

#### ElisaRSR™ Fast 2 Screen ICA™

Correlation:



Comparison:

	ElisaRSR™ 2 Screen ICA™	ElisaRSR™ Fast 2 Screen ICA™	Notes
<b>Total assay time</b>	20 hours	4 hours	
<b>Cut-off</b>	≥ 4.0 u/mL	≥ 4.0 u/mL	As per IFU
<b>Assay sensitivity</b>	90% 45/50 positive	88% 44/50 positive	n = 50 Type 1 DM
n = 50 Type 1 DM	<b>ElisaRSR™ 2 Screen ICA™</b>		
		<b>Negative</b>	<b>Positive</b>
<b>ElisaRSR™ Fast 2 Screen ICA™</b>	<b>Negative</b>	5	1
	<b>Positive</b>	0	44

Concordance rate: 98%