

2 SCREEN ISLET CELL AUTOANTIBODY ELISA KIT**ElisaRSR™ 2 Screen ICA™**

Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD₆₅) and/or IA-2 in serum

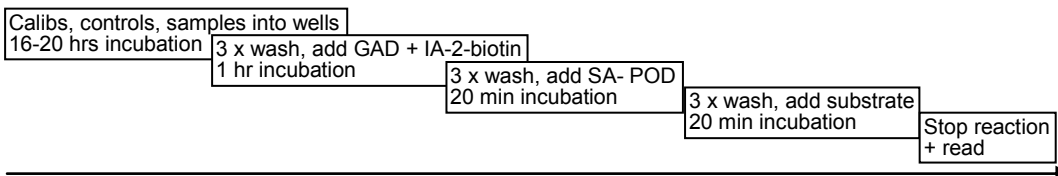
Disease application: Type 1 Diabetes Mellitus (DM)

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

Sample volume: 50µL per well

Total assay time: Approx. 20 hours

Assay method:



Sensitivity: 82% n = 50 for type 1 DM patients (IASP 2012)

Specificity: 100% n = 90 for healthy blood donors (IASP 2012)

Calibrator range: 4 - 450 units/mL (standardised by NIBSC 97/550)

Cut-off: Negative: < 4 unit/mL; Positive: ≥ 4 unit/mL

Lower detection limit: 0.17 units/mL (mean + 2 standard deviations in assay of negative control; n = 30)

Advantages: An easy to use non-isotopic assay suitable for use in routine clinical laboratories in automated or manual formats

Features: Reliable and convenient method to measure specific GAD and/or IA-2 antibodies which are the major component of ICA in type 1 DM. Kit calibrators are NIBSC units i.e. GAD and/or IA-2 antibody levels in test samples are expressed as NIBSC 97/550 units.

A good agreement between ICA measured by immunofluorescence and GAD₆₅ and/or IA-2 Abs measured by 2 Screen ICA ELISA indicating that ElisaRSR™ 2 Screen ICA is a cost effective, high throughput alternative to immunofluorescence for screening large number of samples to identify individuals at risk of progression to type 1 DM.

Note: Sensitivity and specificity were assessed in Islet Autoantibody Standardization Program (IASP) 2012.

Kit size: 96 wells

Order code: 2GI/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

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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