Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD\textsubscript{65}) 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:

1. Calibs, controls, samples into wells
2. 16-20 hrs incubation
3. 3 x wash, add GAD + IA-2-biotin
4. 1 hr incubation
5. 3 x wash, add SA-POD
6. 20 min incubation
7. 3 x wash, add substrate
8. 20 min incubation
9. Stop reaction
10. Read

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 GAD\textsubscript{65} 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:

A sensitive non-isotopic assay for GAD\textsubscript{65} 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\textsubscript{65}