

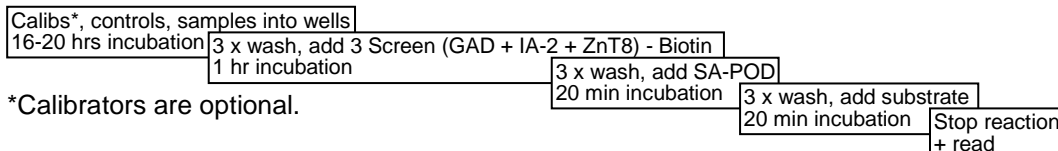
3 SCREEN ISLET CELL ANTIBODY ELISA KIT**ElisaRSR™ 3 Screen ICA™**

98/79/EC

Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD₆₅) and/or IA-2 and/or zinc transporter 8 (ZnT8) in serum.

Disease application: Type 1 Diabetes Mellitus (T1D)

Test samples: Sera may be used. Do not use lipaemic or haemolysed serum samples or plasma samples.
No interference is observed with bilirubin at 20 mg/dL, haemoglobin at 500 mg/dL or intralipid up to 3,000 mg/dL or Biotin at 14 µg/mL

Assay method:

Sample volume: 25 µL per well

Total assay time: Approx. 20 hours

Sensitivity: 92% n = 50 for type 1 DM patients (IASP** 2018)
86% n = 147 for type 1 DM patients (mostly with longstanding disease)

Specificity: 99% n = 90 for adult controls (IASP** 2018)
97% n = 1200 for healthy adult male blood donors
** IASP: Islet Autoantibody Standardization Program

Reference cut-off: Negative: <30 index; Positive: ≥ 30 index [The cut-off is based on 97% of 1200 healthy adult male blood donor sera.]

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 GAD and/or IA-2 and/or ZnT8 antibodies that are the major components of ICA in type 1 DM.
ElisaRSR™ 3 Screen ICA™ is a cost effective, high throughput assay for screening large numbers of samples to identify individuals at risk of progress to type 1 DM. The positive samples measured by ElisaRSR™ 3 Screen ICA™ can be assessed in the three individual antibody assays and also for insulin antibodies.

Size: 96 wells

Order code: 3ZGI/96R (index results; without calibrators)
3ZGI/96 (with calibrators)

Literature: M Amoroso et al, Clin Chim Acta 2016 **462**:60-64
3 Screen islet cell autoantibody ELISA: A sensitive and specific ELISA for the combined measurement of autoantibodies to GAD₆₅, to IA-2 and to ZnT8.
AG Ziegler et al, Diabetes Technol Ther 2016 **18**:687-693
3 Screen ELISA for high-throughput detection of beta cell autoantibodies in capillary blood.

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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04 June 2020
TECH/ElisaRSR 3 Screen ICA Rev 1