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

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1 hr incubation</td>
<td>3 x wash, add 3 Screen (GAD + IA-2 + ZnT8) - Biotin</td>
</tr>
<tr>
<td>20 min incubation</td>
<td>3 x wash, add SA-POD</td>
</tr>
<tr>
<td>20 min incubation</td>
<td>Stop reaction + read</td>
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</table>
*Calibrators are optional.

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 GAD$_{65}$, 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.