**Description:** Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to the zinc transporter 8 (ZnT8) in serum

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

**Test samples:** Sera, citrate plasma and heparin plasma may be used. Do not use lipaemic or haemolysed serum samples. Some EDTA plasma samples may show lower results than those obtained with corresponding serum samples. No interference is observed with bilirubin at 20 mg/dL, haemoglobin at 500 mg/dL or intralipid up to 3,000 mg/dL.

**Sample volume:** 25 µL per well

**Total assay time:** Approx. 20 hours

**Assay method:**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Calibs, controls, samples into wells</td>
</tr>
<tr>
<td></td>
<td>18 hrs incubation</td>
</tr>
<tr>
<td>2</td>
<td>3 x wash, add ZnT8-Biotin</td>
</tr>
<tr>
<td></td>
<td>1 hr incubation</td>
</tr>
<tr>
<td>3</td>
<td>3 x wash, add SA-POD</td>
</tr>
<tr>
<td></td>
<td>20 min incubation</td>
</tr>
<tr>
<td>4</td>
<td>3 x wash, add substrate</td>
</tr>
<tr>
<td></td>
<td>20 min incubation</td>
</tr>
<tr>
<td>5</td>
<td>Stop reaction</td>
</tr>
<tr>
<td></td>
<td>+ read</td>
</tr>
</tbody>
</table>

**Sensitivity:**

- 76% n = 50 for type 1 DM patients (IASP 2015)
- 74% n = 50 for type 1 DM patients (IASP 2013)

**Specificity:**

- 97% n = 90 for healthy blood donors (IASP 2015)
- 99% n = 90 for healthy blood donors (IASP 2013)

**Calibrator range:** 10 - 2000 units/mL (arbitrary RSR units)

**Cut-off:**

- Negative: <15 unit/mL; Positive: ≥15 unit/mL

**Lower detection limit:** 1.2 units/mL (mean + 2 standard deviations in assay of negative control; n = 20)

**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 ZnT8 antibodies which are a major component of ICA in type 1 DM and which are useful for diagnosis and prediction of type 1 DM.

**Note:** Sensitivity and specificity were assessed in Islet Antibody Standardization Program (IASP) 2013 and 2015.

**Kit size:** 96 wells

**Order code:** ZnT8/96

**Literature:**

- J M Wenzlau et al, PNAS 2007 **104**: 17040-17045
  The cation efflux transporter ZnT8 (Slc30A8) is a major autoantigen in human type I diabetes
- P Achenbach et al, Diabetologia 2009 **52**: 1881-1888
  Autoantibodies to zinc transporter 8 and SLC30A8 genotype stratify type 1 diabetes risk
- J M Wenzlau et al, J Clin Endocrinol Metab 2010 **95**: 4712-4719
  Kinetics of the post-onset decline in zinc transporter 8 autoantibodies in type 1 diabetic human subjects
- L Petruzelkova et al, Diabet Med 2014 **31**:165-71
  The dynamic changes of zinc transporter 8 autoantibodies in Czech children from the onset of type 1 diabetes mellitus.
- G Dunseath et al, Clinica Chimica Acta 2015 447:90-95
  Bridging-type enzyme-linked immunoassay for zinc transporter 8 autoantibody measurements in adult patients with diabetes mellitus.