RSR TECHNICAL INFORMATION

FAST ZINC TRANSPORTER 8 (ZnT8) AUTOANTIBODY ELISA KIT ElisaRSR™ Fast ZnT8 Ab™

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 (T1D)
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
Assay method:	Calibs, controls, samples into wells 2 hrs incubation 3 x wash, add ZnT8-Biotin 1 hr incubation 3 x wash, add SA-POD
Assay temperature:	20 – 25 °C 20 min incubation 3 x wash, add substrate 20 min incubation Stop reaction
Total assay time:	Approx. 4 hours
Sensitivity:	n = 50 for type 1 DM patients (IASP 2016 samples)
Specificity:	 97% n = 90 for healthy blood donors (IASP 2016 samples) 99% n = 640 for healthy blood donors
Calibrator range:	10 - 2000 units/mL (arbitrary RSR units)
Cut-off:	Negative: <10 unit/mL; Positive: ≥10 unit/mL
Lower detection limit	 5.0 units/mL (mean + 2 standard deviations in assay of negative control; n = 20) with standard laboratory equipment 2.4 units/mL (mean + 2 standard deviations in assay of negative control; n = 20, performed on Dynex DS2 automated ELISA processor.
Advantages: Features:	An easy to use non-isotopic assay suitable for use in routine clinical laboratories in automated or manual formats. Reliable and convenient method to measure specific ZnT8 antibodies which are a major component of ICA in T1D and which are useful for diagnosis and prediction of T1D.
Note:	Sensitivity and specificity were assessed with Islet Antibody Standardization Program (IASP) 2016 samples.
Kit size:	96 wells
Order code:	FZTE/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.

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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