

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

98/79/EC

- 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	3 x wash, add ZnT8-Biotin	3 x wash, add SA-POD	3 x wash, add substrate	Stop reaction + read
2 hrs incubation	1 hr incubation	20 min incubation	20 min incubation	
- Assay temperature:** 20 – 25 °C
- Total assay time:** Approx. 4 hours
- Sensitivity:** 72% n = 50 for T1D patients positive (IASP 2016 samples)
76% n = 50 for T1D patients positive (IASP 2020 samples)
- Specificity:** 99% n = 640 for healthy blood donors
97% n = 90 for healthy blood donors (IASP 2016 samples)
100% n = 90 for healthy blood donors (IASP 2020 samples)
- 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:** 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 T1D and which are useful for diagnosis and prediction of T1D.
- Note:** Sensitivity and specificity were assessed with Islet Antibody Standardization Program (IASP) 2016 and 2020 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 1 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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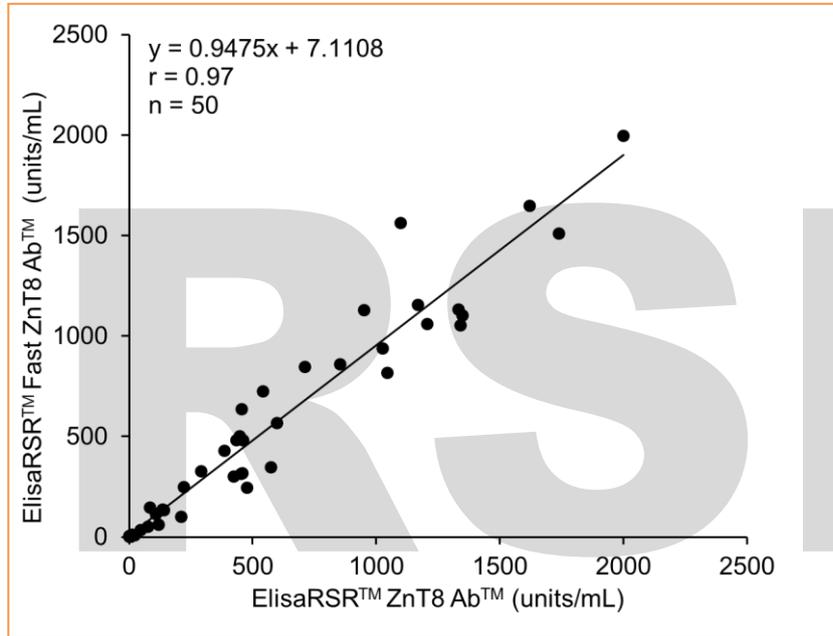
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27 Sep 2021

IFU 38a Rev 3_TECH/ElisaRSR Fast ZnT8 Ab Rev1 1/2

IASP 2020 Results

Correlation:



Comparison:

	ZnT8 Ab	Fast ZnT8 Ab	Note
Total Assay Time	20 hours	4 hours	
Cut off for Positive	≥ 15u/mL	≥ 10u/mL	as recommended in IFU
Assay Sensitivity	74.0%	76.0%	n=50 patients*
	37/50 patients positive	38/50 patients positive	

* 50 T1D patients include 38 new-onset T1D and 12 Stage 2 T1D (pre-clinical T1D) with multiple autoantibodies.

n=50 T1D patients		ElisaRSR™ ZnT8 Ab™	
		Negative	Positive
ElisaRSR™ Fast ZnT8 Ab™	Negative	12	0
	Positive	1	37

Concordance rate: 98.0%

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