

# Zinc Transporter 8 Autoantibody (ZnT8Ab)

## ELISA

### ISLET CELL AUTOIMMUNITY

#### ASSAY CHARACTERISTICS

Semi-Quantitative  
Calibration: 4 Calibrators, 10 - 500 U/mL  
Controls (Included): 2 Positive, 1 Negative

#### TOTAL RUNNING TIME

17 Hours and 40 Minutes

#### SPECIMEN MATRIX

Human Serum

#### REFERENCE RANGE

< 15.0 U/mL: Negative  
≥ 15.0 U/mL: Positive

#### PRECISION

Intra-Assay		Inter-Assay	
Dose (U/mL)	% CV	Dose (U/mL)	% CV
15.4	3.3	16.1	9.8
66.3	2.5	73.7	4.7
222.2	5.3	250.3	17.7

PATIENT GROUP	NUMBER OF PATIENTS POSITIVE FOR ZNT8AB	%
Type 1 Diabetes	220/323	68%
Graves' Disease	1/24	4%
Addison's Disease	2/23	9%
Type 2 Diabetes	1/60	2%
Celiac Disease	0/10	0%
Systemic Lupus Erythematosus	0/9	0%
Metabolic Syndrome	0/37	0%
Kidney Disease	1/10	10%
Healthy Blood Donors	6/447	1%

#### CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity: 68%  
Specificity: 98%

The KRONUS Zinc Transporter 8 Autoantibody (ZnT8Ab) ELISA Assay is for the semi-quantitative determination of autoantibodies to Zinc Transporter 8 (ZnT8) in human serum, and may be useful as an aid in the diagnosis of Type 1 diabetes mellitus (autoimmune mediated diabetes). The ZnT8Ab assay is not to be used alone and is to be used in conjunction with other clinical and laboratory findings.

Type 1 diabetes mellitus (T1DM) is the result of autoimmune destruction of the insulin-producing  $\beta$  cells in the pancreatic islets and subsequent loss of insulin secretion. Measurement of islet autoantibodies has become a useful clinical tool for the diagnosis of patients with diabetes.

Zinc transporter 8 (ZnT8) is a member of the large cation efflux family and is one of the major targets of type 1 diabetes autoimmunity. ZnT8 autoantibodies may be present in patients diagnosed with diabetes and are useful as a marker for T1DM testing.

The KRONUS Zinc Transporter 8 Autoantibody (ZnT8Ab) ELISA assay depends on the ability of ZnT8 autoantibodies to act divalently and form a bridge between ZnT8 coated on the ELISA plate wells and liquid phase ZnT8-biotin. The ZnT8-biotin bound is then quantitated by addition of streptavidin peroxidase and a colorogenic substrate (TMB) with reading of the final absorbances at 450nm. The absorbance of each well is directly proportional to the amount of antibody present.

#### ORDERING INFORMATION

KR7730 — 96 Well Kit



For In Vitro Diagnostic Use, Rx Only



## ASSAY PROCEDURE

Sample Volume: 25  $\mu$ L per Well

Calibrators, Controls and Samples into Coated Wells: 25  $\mu$ L  
Overnight Incubation at 2 - 8° C  
Wash Wells 3 Times

ZnT8-Biotin: 100  $\mu$ L  
1 Hour Incubation at 2 - 8° C  
Wash Wells 3 Times

SA-POD: 100  $\mu$ L  
20 Minute Incubation with Shaking at Room Temperature  
Wash Wells 3 Times

TMB Substrate: 100  $\mu$ L  
20 Minute Incubation in the Dark at Room Temperature

Stop Solution: 100  $\mu$ L  
Read Absorbance at 450nm

Total Assay Time is Approximately 17 Hours and 40 Minutes

## REFERENCES

1. Wenzlau JM, Juhl K, Yu L, Moua O, Sarkar SA, Gottlieb P, Rewers M, Eisenbarth GS, Jensen J, Davidson HW, Hutton JC. The cation efflux transporter ZnT8 (Slc30A8) is a major autoantigen in human type 1 diabetes. Proc Natl Acad Sci USA. 2007 Oct 23;104(43):17040-17045.
2. Wenzlau JM, Walter M, Gardner TJ, Frisch LM, Yu L, Eisenbarth GS, Ziegler AG, Davidson HW, Hutton JC. Kinetics of the post-onset decline in zinc transporter 8 autoantibodies in type 1 diabetic human subjects. J Clin Endocrinol Metab. 2010 Oct;95(10):4712-4719.
3. Wenzlau JM, Moua O, Sarkar SA, Yu L, Rewers M, Eisenbarth GS, Davidson HW, Hutton JC. SIC30A8 is a major target of humoral autoimmunity in type 1 diabetes and a predictive marker in prediabetes. Ann NY Acad Sci. 2008 Dec;1150:256-258.
4. Dang M, Rockell J, Wagner R, Wenzlau JM, Yu L, Hutton JC, Gottlieb PA, Davidson HW. Human type 1 diabetes is associated with T cell autoimmunity to zinc transporter 8. J Immunol. 2011 May;186(10):6056-6063.



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