IA-2 Autoantibody (IA-2Ab)

ELISA

ISLET CELL AUTOIMMUNITY

ASSAY CHARACTERISTICS

Quantitative

Calibration:	5 Calibrators, 0.75 – 350 U/mL NIBSC 97/550
Controls (Included):	1 Positive, 1 Negative

TOTAL RUNNING TIME

17 Hours and 40 Minutes

SPECIMEN MATRIX

Human Serum

REFERENCE RANGE

< 7.5 U/mL: Negative
≥ 7.5 U/mL: Positive

PRECISION

Intra-Assay Dose (U/mL)	% CV	Inter-Assay Dose (U/mL)	% CV
7.3	6.69	7.3	9.69
28.1	5.05	28.1	6.46
82.9	2.89	82.9	4.92

PATIENT GROUP	NUMBER OF PATIENTS POSITIVE FOR IA-2 AB	%
Type 1 Diabetes	139/239	58.2
LADA	10/45	22.2
Type 2 Diabetes	2/57	3.5
Rheumatoid Arthritis	1/20	5.0
Hashimoto's thyroiditis	1/20	5.0
Graves' Disease	0/19	0.0
Systemic Lupus Erythematosus	0/14	0.0
Metabolic Syndrome	1/35	2.8
Addison's Disease	3/27	11.1
Celiac Disease	0/50	0.0
Healthy Blood Donors	14/718	1.9

CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity	58.2%
Specificity	97.0%

ORDERING INFORMATION

KR7755 — 96 Well Kit

The KRONUS IA-2 Autoantibody (IA-2Ab) ELISA Kit is for the quantitative determination of autoantibodies to Islet Antigen-2 (IA-2) in human serum and may be useful as an aid in the diagnosis of Type 1 diabetes mellitus (autoimmune mediated diabetes). The IA-2Ab ELISA Kit is not to be used alone and is to be used in conjunction with other clinical and laboratory findings.

The KRONUS IA-2Ab ELISA Kit depends on the ability of IA-2 autoantibodies to act divalently, forming a bridge between IA-2 coated on ELISA plate wells and liquid phase IA-2-biotin. The resulting antigen-antibody-antigen complexes are then quantitated by the addition of streptavidin peroxidase (SA-POD) and tetramethylbenzidine (TMB) to produce a colorogenic reaction. Stop solution is added to halt the reaction and absorbance is read using an ELISA plate reader. The absorbance of each well is directly proportional to the amount of antibody present. IA-2Ab levels are derived from a standard curve, traceable to the WHO reference preparation NIBSC 97/550 and expressed in U/mL.

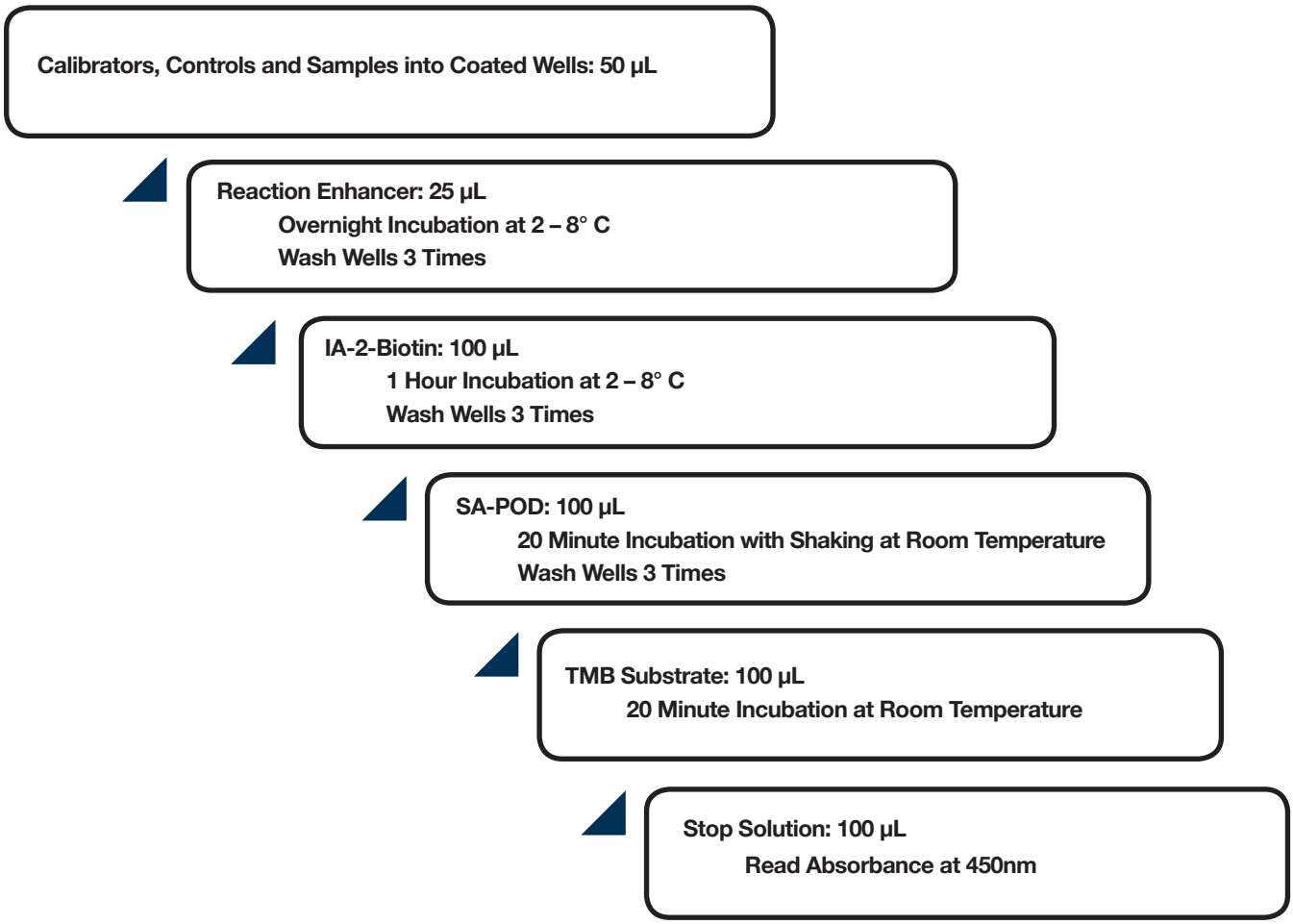
For In Vitro Diagnostic Use. Rx Only.

KRONUS

800.4.KRONUS (800.457.6687) | 208.377.4800 | www.kronus.com | kronus@kronus.com

ASSAY PROCEDURE

Sample Volume: 50 µL per Well



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KRONUS …Your Source for Sensitive Autoimmune Diagnostics