Insulin Autoantibody (IAA)

RADIOIMMUNOASSAY

ISLET CELL AUTOIMMUNITY

ASSAY CHARACTERISTICS

Semi-Quantitative
Calibration: 5 Calibrators, 0 - 50 U/mL
Controls (Included): 2 Positive

TOTAL RUNNING TIME

17 Hours and 40 Minutes

SPECIMEN MATRIX

Human Serum

REFERENCE RANGE

> 0.4 U/mL: Positive

PRECISION

Intra-Assay Dose (U/mL)	% CV	Inter-Assay Dose (U/mL)	% CV
6.5	7.8	6.4	15.4
0.47	9.0	0.48	9.1

PATIENT GROUP	NUMBER OF PATIENTS POSITIVE FOR IAA	%
Type 1 Diabetes	40/80	50%
Graves' Disease	0/17	0%
Celiac Disease	0/10	0%
Hashimoto's Thyroiditis	0/20	0%
Systemic Lupus Erythematosus	0/10	0%
Rheumatoid Arthritis	0/10	0%
Healthy Blood Donors	3/150	2%

CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity: 50%
Specificity: 99%

ORDERING INFORMATION

KR6790 — 100 Tube Kit

The KRONUS Insulin Autoantibody (IAA) RIA Assay Kit is for the semi-quantitative determination of antibodies to insulin in human serum, and is useful as an aid in the diagnosis of Type 1 diabetes mellitus (autoimmune mediated diabetes) in patients who have not received insulin therapy.

As the KRONUS IAA RIA assay kit does not discriminate between insulin autoantibodies and antibodies produced in response to exogenous insulin therapy, measurement of autoantibodies to insulin must be done prior to insulin therapy. Once insulin therapy has begun, antibodies may form against the therapeutic insulin that will be detected by the KRONUS IAA RIA assay.

Diabetes mellitus is generally classified as either Type 1 (insulin dependent diabetes mellitus) or Type 2 (non-insulin dependent diabetes mellitus). In most instances, the onset of type 1 diabetes (IDDM) is the result of autoimmune destruction of insulin-producing beta cells in the pancreatic islets and the ensuing loss of endogenous insulin secretion.

Autoantibodies to insulin are among the first sets of anti-islet autoantibodies to appear in patients developing type 1 diabetes and are frequently associated with newly diagnosed untreated insulin dependent diabetics. Measurement of these immunologic markers has been shown to be of considerable value in assisting the attending clinician with the diagnosis of patients, especially children, with diabetes.

For In Vitro Diagnostic Use

KRONUS

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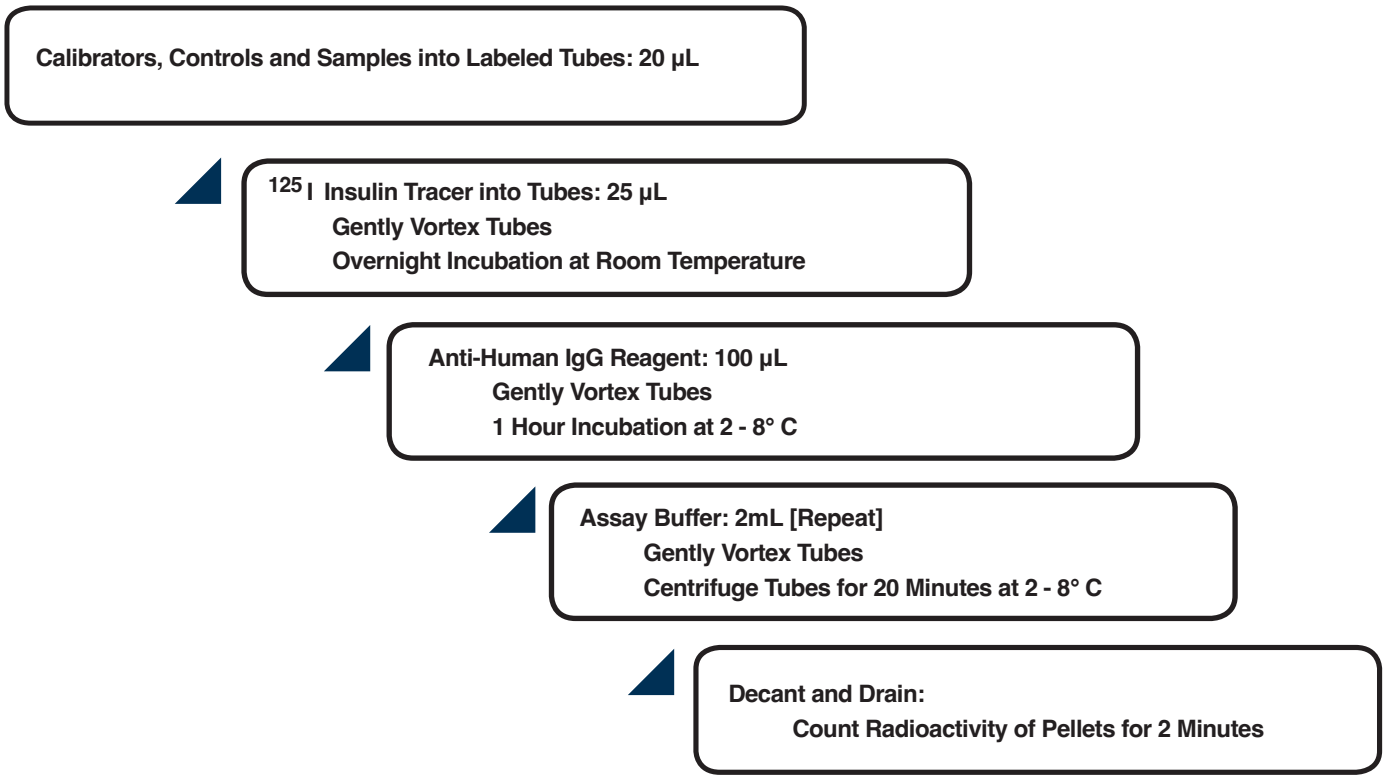
ASSAY PROCEDURE

Sample Volume: 20 µL per Tube



Total Assay Time is Approximately 17 Hours and 40 Minutes

REFERENCES

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5. Sutton M, Klaff LJ, Asplin CM, Clemons P, Tatpati O, Lyen K, Raghu P, Baker L, Guthrie R, Sperling M, et al. Insulin autoantibodies at diagnosis of insulin-dependent diabetes: effect on the antibody response to insulin treatment. Metabolis. 1988 Nov;37(11):1005-1007.
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7. Winter WE, Harris N, Schatz D. Type 1 diabetes islet autoantibody markers. Diabetes Technol Ther. 2002 Jul;4(6):817–839.

KRONUS …Your Source for Sensitive Autoimmune Diagnostics