

Description: Radioimmunoassay (RIA) kit for the quantitative determination of autoantibodies to insulin in serum

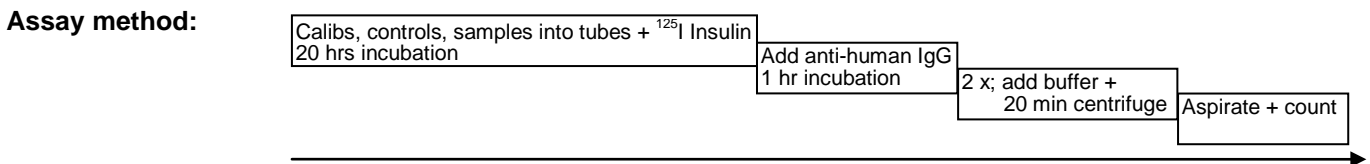
Disease application: Type 1 Diabetes Mellitus (DM)

Test samples: Sera can be used. Do not use lipaemic or haemolysed serum samples. No interference was observed with bilirubin at 20 mg/dL and intralipid up to 3,000 mg/dL. Interference was observed with haemoglobin at 500 mg/dL.

Assay tubes: Polypropylene tubes, 3.5mL, 55 x 12 mm

Sample volume: 20 µL per tube

Total assay time: Approx. 24 hours



Sensitivity: 32% n = 50 for type 1 DM patients (DASP 2009)
38% n = 49 for type 1 DM patients (DASP 2007)

Specificity: 99% n = 91 for healthy blood donors (DASP 2009)
96% n = 100 for healthy blood donors (DASP 2007)

Calibrator range: 0.4 - 50 units/mL (arbitrary RSR units)

Cut-off: Negative: <0.4 unit/mL; Positive: ≥0.4 unit/mL

Lower detection limit: 0.03 units/mL (mean + 2 standard deviations in assay of negative control; n = 21)

Advantages: Easy assay format suitable for use in routine clinical laboratories. Only 20 µL of test sample required for the assay which can be completed in 24 hours.

Features: Reliable and convenient method to measure specific insulin autoantibodies which are makers of type 1 DM (prior to insulin therapy) and are useful for diagnosis and prediction of type 1 DM.

Note: For samples with low levels of IAA, assay using RSR unlabelled recombinant insulin to be offered in order to check specificity. Sensitivity and specificity were assessed in Diabetes Antibody Standardization Program (DASP) 2007 and 2009

Kit size: 50 tubes, 100 tubes

Order code: IAA/50, IAA/100

Literature: A Williams et al, Journal of Autoimmunity 1997 **10**: 473-478
A novel micro-assay for insulin autoantibodies

M Masuda et al, Clinica Chimica Acta 2000 **291**: 53-56
Autoantibodies to IA-2 in insulin-dependent diabetes mellitus. Measurements with a new immunoprecipitation assay

S Chen et al, Clinica Chimica Acta 2005 **357**: 74-83
Sensitive non-isotopic assays for autoantibodies to IA-2 and to a combination of both IA-2 and GAD₆₅

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.