RSR

TECHNICAL INFORMATION

IA-2 AUTOANTIBODY (VERSION 2) ELISA KIT

ElisaRSR™ IA-2 Ab Version 2

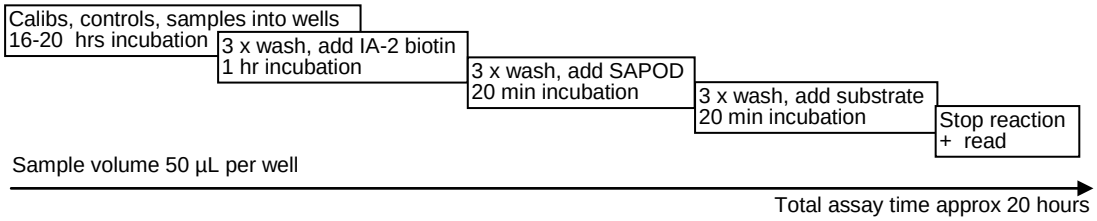
CE

98/79/EC

Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to IA-2 in serum

Disease application: Type 1 Diabetes Mellitus (DM)

Assay method:



Sensitivity: 64% n = 50 for type 1 DM patients (DASP 2010)
60% n = 50 for type 1 DM patients (DASP 2009)

Specificity: 100% n = 90 for healthy blood donors (DASP 2010)
100% n = 94 for healthy blood donors (DASP 2009)

Calibrator range: 7.5 - 4000 units/mL (standardised by NIBSC 97/550)

Cut-off: Negative: <7.5 unit/mL; Positive: ≥7.5 unit/mL

Lower detection limit: 1.25 units/mL (mean + 2 standard deviations in assay of negative control; n = 20)

Advantages: A non-isotopic assay with easy to use format for use in routine clinical laboratories and suitable for automated systems. It offers similar disease specificity and sensitivity to RiaRSR™ IA-2 Ab.

Features: Reliable and convenient method to measure specific IA-2 antibodies which are an important component of ICA in type 1 DM. Kit calibrators are NIBSC units i.e. IA-2 Ab levels in test samples are expressed as NIBSC 97/550 units. IA-2 Ab measurements are useful for diagnosis and prediction of type 1 DM.

Note: Sensitivity and specificity were assessed in Diabetes Antibody Standardization Program (DASP) 2009 and 2010

Kit size: 96 wells

Order code: IAE/96/2

Literature: "Sensitive non-isotopic assays for autoantibodies to IA-2 and to a combination of both IA-2 and GAD_{65}"
S. Chen et al
Clinica Chimica Acta 2005 **357**: 74-83

RSR

This kit is intended for in-vitro us 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.

RSR Limited
Diagnostics for Autoimmunity
Avenue Park Pentwyn, Cardiff, CF23 8HE United Kingdom Tel: +44 (0) 29 2073 2076
http://www.rsrltd.com E-mail: info@rsrltd.com Fax: +44 (0) 29 2073 2704

©2010 RSR Limited All Rights Reserved