RSR

TECHNICAL INFORMATION

3 SCREEN ISLET CELL ANTIBODY ELISA KIT

ElisaRSR™ 3 Screen ICA™

Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD<sub>65</sub>) and/or IA-2 and/or zinc transporter 8 (ZnT8) in serum.

Disease application: Type 1 Diabetes Mellitus (DM)

Test samples: Sera may be used. Do not use lipaemic or haemolysed serum samples or plasma samples.

Sample volume: 25 µL per well

Total assay time: Approx. 20 hours

Assay method:

1. 16-20 hrs incubation
2. 3 x wash, add 3 Screen (GAD + IA-2 + ZnT8) - Biotin
3. 1 hr incubation
4. 3 x wash, add SA-POD
5. 20 min incubation
6. 3 x wash, add substrate
7. 20 min incubation
8. Stop reaction + read

*Calibrators are optional.

Sensitivity:
- 94% n = 50 for type 1 DM patients (IASP** 2015)
- 86% n = 147 for type 1 DM patients (mostly with longstanding disease)

Specificity:
- 96% n = 90 for adult controls (IASP** 2015)
- 97% n = 1200 for healthy adult male blood donors

** IASP: Islet Autoantibody Standardization Program

Reference cut-off:
- Negative: <30 index
- Positive: ≥ 30 index [The cut-off is based on 97% of 1200 healthy adult male blood donor sera.]

Advantages:
- An easy to use non-isotopic assay suitable for use in routine clinical laboratories in automated or manual formats.

Features:
- Reliable and convenient method to measure GAD and/or IA-2 and/or ZnT8 antibodies that are the major components of ICA in type 1 DM.
- ElisaRSR™ 3 Screen ICA™ is a cost effective, high throughput assay for screening large numbers of samples to identify individuals at risk of progress to type 1 DM. The positive samples measured by ElisaRSR™ 3 Screen ICA™ can be assessed in the three individual antibody assays and also for insulin antibodies.

Size:
- 96 wells

Order code:
- 3ZGI/96

Literature:
- M Amoroso et al, Clin Chim Acta 2016 462:60-64
- 3 Screen islet cell autoantibody ELISA: A sensitive and specific ELISA for the combined measurement of autoantibodies to GAD<sub>65</sub>, to IA-2 and to ZnT8.
- AG Ziegler et al, Diabetes Technol Ther DOI: 10.1089/dia.2016.0199 (in press)
- 3 Screen ELISA for high-throughput detection of beta cell autoantibodies in capillary blood.