RSR

TECHNICAL INFORMATION

GLUTAMIC ACID DECARBOXYLASE (GAD) AUTOANTIBODY ELISA KIT

ElisaRSR™ GADAb

Description: Enzyme linked immunosorbent assay (ELISA) kit for the quantitative determination of autoantibodies to glutamic acid decarboxylase (GAD_{65}) in serum

Disease application: Type 1 Diabetes Mellitus (DM)

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

No interference was observed with bilirubin at 20 mg/dL, haemoglobin at 500 mg/dL or intralipid up to 3,000 mg/dL.

Sample volume: 25 µL per well

Total assay time: Approx. 3 hours

Assay method:

1 hr incubation
3 x wash, add GAD-biotin
1 hr incubation
3 x wash, add SA-POD
20 min incubation
3 x wash, add substrate
20 min incubation
Stop reaction
+ read

Sensitivity:

- 78% n = 50 for type 1 DM patients (IASP 2013)
- 74% n = 50 for type 1 DM patients (IASP 2012)
- 90% n = 50 for type 1 DM patients (DASP 2010)

Specificity:

- 98% n = 90 for healthy blood donors (IASP 2013)
- 99% n = 90 for healthy blood donors (IASP 2012)
- 94% n = 90 for healthy blood donors (DASP 2010)

Calibrator range: 5 - 2000 units/mL (standardised with NIBSC 97/550)

Cut-off: Negative: <5 unit/mL; Positive: ≥ 5 unit/mL

Lower detection limit: 0.57 units/mL (mean + 2 standard deviations in assay of negative control; n = 20)

Advantages:

A non-isotopic method with easy assay format for use in routine clinical laboratories and suitable for automated systems. It offers even higher disease specificity and sensitivity than RiaRSR™ GADAb.

Features:

Reliable and convenient method to measure specific GAD antibodies which are a major component of ICA in type 1 DM. GADAb levels in test samples are expressed as NIBSC 97/550 units (www.nibsc.ac.uk). GADAb measurements are useful for diagnosis and prediction of type 1 DM.

Note:

For samples with low levels of GADAb, assay with & without RSR unlabelled recombinant GAD in order to check specificity.

Sensitivity and specificity were assessed in Diabetes Antibody Standardization Program (DASP) 2010, Islet Autoantibody Standardization Program (IASP) 2012 and IASP 2013.

RSR participates in the UK NEQAS (national external quality assessment service) scheme.

Kit size: 96 wells

Order code: GDE/96

Literature:

- A sensitive non-isotopic assay for GAD_{65} autoantibodies
- 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 GAD_{65}

Stiff-person syndrome (SPS):

- ElisaRSR™ GADAb may be used to detect SPS for research use only. See for example: -
- GAD antibody-associated neurological illness and its relationship to gluten sensitivity

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.

RSR Limited

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TECH/ElisaRSR GADAb Rev3

1/2
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ElisaRSR™ GADAb

Correlation:

1 unit/mL (RiaRSR™ GADAb) = 25 units/mL (approximately) of NIBSC 97/550 Units/mL (ElisaRSR™ GADAb); standardised with NIBSC 97/550

Comparison:

<table>
<thead>
<tr>
<th>n=50 type 1 DM patients</th>
<th>RiaRSR™ GADAb</th>
</tr>
</thead>
<tbody>
<tr>
<td>ElisaRSR™ GADAb</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>11</td>
</tr>
<tr>
<td>Positive</td>
<td>4</td>
</tr>
<tr>
<td>Concordance rate:</td>
<td>92.0%</td>
</tr>
</tbody>
</table>

Measurements in different patient groups:

GAD65 Ab levels measured by ELISA in different patient groups. HBD = healthy blood donors, SLE = systemic lupus erythematosus, RA = rheumatoid arthritis. O = sera positive in GAD65 Ab ELISA but negative in the 125I-GAD65 RIA.

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