PRODUCT SPECIFICATIONS

Name: Anti-\(h\) C-Peptide 9103 SPRN-5

Specificity: Antibody recognizes human C-peptide

Description: Monoclonal mouse antibody, cultured \textit{in vitro} under conditions free from animal-derived components

Product code: 100114

Product buffer solution: 37 mM citrate, 125 mM phosphate, pH 6.0, 0.9 % NaCl, 0.095 % NaN\(_3\) as a preservative

Shelf life and storage: 24 months from manufacturing at 2–8 °C

Analyte description: C-peptide is produced when proinsulin is split into insulin and C-peptide. They split before proinsulin is released from endocytic vesicles within the pancreas—one C-peptide for each insulin molecule. When a patient has newly diagnosed type 1 or type 2 diabetes, C-peptide can be used to help determine how much insulin the patient’s pancreas is still producing. C-peptide measurements also can be used in conjunction with insulin and glucose levels to help diagnose the cause of documented hypoglycemia and to monitor its treatment.

PARAMETERS TESTED ON EACH LOT

Product appearance: Liquid, may turn slightly opaque during storage

Product concentration: 5.0 mg/ml (+/- 10 %)

Immunoreactivity: 80–120 % compared to the reference sample in an FIA test

IEF Profile: 6.6 – 7.7

Purity: \(\geq 95\ %\)

PARAMETERS DETERMINED DURING PRODUCT DEVELOPMENT

Subclass: IgG\(_1\)

Association rate constant: Not Determined (N/D)

Dissociation rate constant: N/D

Affinity constant: \(1 \times 10^8 \text{ l/mol}\)

Determination method: Radioimmunoassay (RIA)

Determination antigen: C–Peptide, Proinsulin [33–63], human C–Peptide, American Peptide Company (Cat 20–1–11, Lot 010116A1)
Cross-reactivities

Human proinsulin (recombinant) 18% (Sigma, Cat P4672, Lot 5740974)

Epitope

The binding site is located within the range 4–19, with the most critical amino acids being DL (4–5).

Pair recommendations

<table>
<thead>
<tr>
<th>CAPTURE ANTIBODY</th>
<th>DETECTION ANTIBODY</th>
</tr>
</thead>
<tbody>
<tr>
<td>9101</td>
<td>9103</td>
</tr>
</tbody>
</table>

Please note that pair recommendations are based on results obtained by our laboratory. Equally good results may be obtained using other pairs and therefore these recommendations are only indicative.

Product stability

<table>
<thead>
<tr>
<th>TEMPERATURE, TIME</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>-70 °C, 21 days</td>
<td>Failed due to reduced antigen binding</td>
</tr>
<tr>
<td>-20 °C, 21 days</td>
<td>Failed due to aggregation</td>
</tr>
<tr>
<td>+4 °C, 21 days</td>
<td>OK</td>
</tr>
<tr>
<td>+25 °C, 21 days</td>
<td>OK</td>
</tr>
<tr>
<td>+35 °C, 7 days</td>
<td>OK</td>
</tr>
<tr>
<td>+35 °C, 21 days</td>
<td>Failed due to reduced antigen binding</td>
</tr>
<tr>
<td>+45 °C, 3 days</td>
<td>Failed due to reduced antigen binding</td>
</tr>
<tr>
<td>+45 °C, 7 days</td>
<td>Failed due to reduced antigen binding</td>
</tr>
</tbody>
</table>

Stability testing is performed in the product buffer to see whether different temperatures affect the antigen binding, charge or composition of the antibody. Please note that the shelf life given on the first page is based on real time stability testing at 2–8 °C in the product buffer.

Miscellaneous

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References

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