

PRODUCT SPECIFICATIONS

Date: 2011-08-12

PRODUCT NAME	: Anti-h C-Peptide 9101 SPTN-5
PRODUCT SPECIFICITY	: Antibody recognizes human C-Peptide
PRODUCT CODE	: 100113
PRODUCT BUFFER	: 50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.1 % 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 FROM EACH LOT

PRODUCT APPEARANCE	: Clear liquid
PRODUCT CONCENTRATION	: 5.0 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	: 80-120 % compared to reference in an IFMA-test
IEF-RANGE	: 6.4 - 7.9
PURITY	: ≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	: IgG ₁
ASSOCIATION CONSTANT	: N/D
DISSOCIATION CONSTANT	: N/D
AFFINITY CONSTANT	: 7 x 10 ⁹ l/mol
DETERMINATION METHOD	: Radioimmunoassay (RIA)
ANTIGEN	: C-Peptide, Proinsulin [33-63], human C-Peptide, American Peptide Company (Cat No 20-1-11 Lot 010116A1)
CROSS-REACTIVITIES	: Human proinsulin (recombinant) 0.93 % (Sigma Cat No P-4672 Lot 5740974)

EPITOPE : N/D

EPITOPE GROUP : -

Two antibodies binding to the same, or closely located epitopes, belong to the same group and hence cannot be used as a pair in a sandwich assay. Epitope group numbering does not give any detailed information where the epitope is located.

PAIR RECOMMENDATIONS :

SOLID	LABEL
9101	9103

Please note that pair recommendations are based on results obtained in our laboratory. Equally good results may be obtained using other pairs and therefore these recommendations should be taken only as a directive.

PRODUCT STABILITY :

TEMPERATURE, DAYS	RESULT
-70 °C, 21 days	N/D
-20 °C, 21 days	OK
+4 °C, 21 days	OK
+30 °C, 21 days	OK
+35 °C, 21 days	OK
+45 °C, 3 days	OK
+45 °C, 7 days	Failed due to reduced antigen binding

Please note that the shelf life given on page one is based on real time stability testing at +2-8 °C in the product buffer.

Stability testing is performed in the product buffer to see whether different temperatures affect the antigen binding, charge or composition of the antibody. The maximum duration of the test is 21 days, except for the +45 °C only 7 days.

pH, 14 DAYS, +4 °C	RESULT
5.0	OK
6.0	OK
7.0	N/D
8.0	N/D

Stability testing is performed to see whether pH affects the antigen binding, charge or composition of the antibody during 14 days at +4 °C.

MISCELLANEOUS : -

REFERENCES : -

Legal disclaimer

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