

PRODUCT SPECIFICATIONS

Date: 2014-12-19

PRODUCT NAME	:	Anti-h HbA1c 2403 SPTN-5
PRODUCT SPECIFICITY	:	Human glycated Hemoglobin A1
PRODUCT CODE	:	100301
PRODUCT BUFFER	:	50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.095 % NaN ₃ as a preservative
SHELF LIFE AND STORAGE	:	18 months at 2-8 °C
ANALYTE DESCRIPTION	:	Glycated hemoglobin (HbA1c) is formed in a non-enzymatic process during exposure to plasma glucose. Normal levels of glucose produce a normal amount of glycated hemoglobin. As the average amount of plasma glucose increases, the fraction of glycated hemoglobin increases in a predictable way. This serves as a marker for average blood glucose levels over the previous months prior to the measurement. The 2010 American Diabetes Association Standards of Medical Care in Diabetes added the HbA1c ≥ 48 mmol/mol ($\geq 6.5\%$) as another criterion for the diagnosis of diabetes.

PARAMETERS TESTED FROM EACH LOT

PRODUCT APPEARANCE	:	Clear liquid, may precipitate during storage which does not alter the product specifications. Precipitate can be removed by centrifugation or filtering.
PRODUCT CONCENTRATION	:	5.0 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	:	80 – 120 % compared to reference in an IFMA-test
IEF-RANGE	:	7.2 – 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	:	N/D
DETERMINATION METHOD	:	-
ANTIGEN	:	-
CROSS-REACTIVITIES	:	No cross-reactivity against non-glycated hemoglobin A1

EPITOPE : N-terminal end of the beta-chain

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
	2403	7202, 7204

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
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.	-70 °C, 21 days	OK
	-20 °C, 21 days	OK
	+4 °C, 21 days	OK
	+35 °C, 21 days	OK
	+45 °C, 7 days	OK

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.

MISCELLANEOUS : -

REFERENCES : -

Legal disclaimer

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