

## PRODUCT SPECIFICATIONS

Date: 2013-05-06

<b>PRODUCT NAME</b>	:	Anti-h NSE 9602 SPTN-1
<b>PRODUCT SPECIFICITY</b>	:	Antibody recognizes human Neuron-Specific Enolase, $\gamma$ -isoform
<b>PRODUCT CODE</b>	:	100116
<b>PRODUCT BUFFER</b>	:	50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	:	24 months from manufacturing at 2-8 °C
<b>ANALYTE DESCRIPTION</b>	:	Neuron-specific enolase (NSE) has been detected in patients with certain tumors, namely: neuroblastoma, small cell lung cancer, medullary thyroid cancer, carcinoid tumors, pancreatic endocrine tumors, and melanoma. Studies of NSE as a tumor marker have concentrated primarily on patients with neuroblastoma and small cell lung cancer. Measurement of NSE levels in patients with these two diseases can provide information about the extent of the disease and the patient's prognosis, as well as about the patient's response to treatment.

### PARAMETERS TESTED FROM EACH LOT

<b>PRODUCT APPEARANCE</b>	:	Clear liquid
<b>PRODUCT CONCENTRATION</b>	:	1.00 mg/ml (+/- 10 %)
<b>PRODUCT ACTIVITY</b>	:	80-120 % compared to reference in an IFMA-test
<b>IEF-RANGE</b>	:	6.6 – 8.0
<b>PURITY</b>	:	≥ 95 %

### PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

<b>CLASS AND SUBCLASS</b>	:	IgG <sub>1</sub>
<b>ASSOCIATION CONSTANT</b>	:	N/D
<b>DISSOCIATION CONSTANT</b>	:	N/D
<b>AFFINITY CONSTANT</b>	:	2.2 x 10 <sup>8</sup> l/mol
<b>DETERMINATION METHOD</b>	:	SPR analysis (Biacore)
<b>ANTIGEN</b>	:	NSE, Scripps Laboratories (Cat No N0224 Lot BF249001)
<b>CROSS-REACTIVITIES</b>	:	NNE (non-neuronal enolase) < 1.4 %

**EPITOPE** : See reference

**EPITOPE GROUP** : Group B

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
9602	9601
9601	9602

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	N/D
+4 °C, 21 days	N/D
+25 °C, 21 days	N/D
+35 °C, 7 days	N/D
+35 °C, 21 days	N/D
+45 °C, 3 days	N/D
+45 °C, 7 days	N/D

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	N/D
6.0	N/D
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** : Note that antibody binding requires Mg<sup>2+</sup>-ions and is sensitive to chelating agents (EDTA, EGTA, citrate).

**REFERENCES** : Paus, E., Hirzel, K., Lidqvist, M., Höyhty, M., and Warren, D.J. (2011) TD-12 workshop report: characterization of monoclonal antibodies to neuron-specific enolase. Tumor Biol. 32:819-829.

### Legal disclaimer

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