

PRODUCT SPECIFICATIONS

Date: 2011-12-07

PRODUCT NAME	: Anti-h TSH 5408 SPTN-1
PRODUCT SPECIFICITY	: Antibody recognizes human Thyrotropin and its beta chain
PRODUCT CODE	: 100033
PRODUCT BUFFER	: 50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.1 % NaN ₃ as a preservative
SHELF LIFE AND STORAGE	: 36 months from manufacturing at 2-8 °C
ANALYTE DESCRIPTION	: Thyroid-stimulating hormone (also known as TSH or thyrotropin) is a peptide hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland which regulates the endocrine function of the thyroid gland. TSH levels are tested in the blood of patients suspected of suffering from excess (hyperthyroidism), or deficiency (hypothyroidism) of thyroid hormone.

PARAMETERS TESTED FROM EACH LOT

PRODUCT APPEARANCE	: Clear liquid
PRODUCT CONCENTRATION	: 1.00 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	: 80-120 % compared to reference in an IFMA-test
IEF-RANGE	: 6.6 - 7.2
PURITY	: ≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	: IgG ₁
ASSOCIATION CONSTANT	: 9.6×10^5
DISSOCIATION CONSTANT	: 3.8×10^{-5}
AFFINITY CONSTANT	: $K_A = 2.5 \times 10^{10}$ 1/M; $K_D = 4.0 \times 10^{-11}$ M (= 0.04 nM)
DETERMINATION METHOD	: SPR analysis (ProteOn XPR36)
ANTIGEN	: TSH, Scripps TO114, lot.2414402
CROSS-REACTIVITIES	: TSH α < 0.08 % (Scripps Laboratories Cat No T0214 Lot BE298774) hCG < 0.08 % (Scripps Laboratories Cat No C0714 Lot BB274002) LH < 0.08 % (Scripps Laboratories Cat No L0815 Lot BB236003) FSH < 0.08 % (Scripps Laboratories Cat No F0614 Lot BA127003)

EPITOPE : N/A

EPITOPE GROUP : Group 1

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
	5401	5408
	5403	5408
	5405	5408
	5407	5408

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	N/D
	-20 °C, 21 days	OK
	+4 °C, 21 days	OK
	+30 °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.

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 : -

REFERENCES : -

Legal disclaimer

MedixMAB monoclonal antibodies meet their specifications if transported, stored and used according to the instructions for use. See also separate *Notes on use and storage of monoclonal antibodies*. If not otherwise agreed in writing all products are sold under *General Delivery Terms*. Other terms may apply if MedixMAB monoclonal antibodies are purchased from an official distributor of Medix Biochemica products. MedixMAB is a registered trademark of Medix Biochemica and may not be used or reproduced without Medix Biochemica's written permission. Further information on products and methods is available from medixMAB website and extranet.