

PRODUCT SPECIFICATIONS

Date: 2013-10-22

PRODUCT NAME	: Anti-h TSH 5405 SP-1
PRODUCT SPECIFICITY	: Antibody recognizes human Thyrotropin and its beta chain
PRODUCT CODE	: 100030
PRODUCT BUFFER	: 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	: 5.8 - 6.9
PURITY	: ≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	: IgG _{2a}
ASSOCIATION CONSTANT	: 1.2×10^6
DISSOCIATION CONSTANT	: 1.9×10^{-4}
AFFINITY CONSTANT	: KA = 6.6×10^9 1/M; KD = 1.5×10^{-10} M (= 0.15 nM)
DETERMINATION METHOD	: SPR analysis (ProteOn XPR36)
ANTIGEN	: TSH, Scripps TO114, lot.2414402
CROSS-REACTIVITIES	: TSH α 9.3 % (Scripps Laboratories Cat No T0214 Lot 308711) hCG < 0.1 % (Scripps Laboratories Cat No C0714 Lot 191712) LH 0.47 % (Scripps Laboratories Cat No L0814 Lot 125711) FSH 1.8 % (Scripps Laboratories Cat No F0614 Lot 805811)

EPITOPE : N/A

EPITOPE GROUP : Group 3

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
	5405	5409
	5405	5408
	5404	5405

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	Failed due to charge changes
	+35 °C, 7 days	Failed due to charge changes
	+35 °C, 21 days	Failed due to charge changes
	+45 °C, 3 days	Failed due to aggregation
	+45 °C, 7 days	Failed due to reduced antigen binding

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 : Wu et al. (2002) developed a three antibody assay system which utilizes clones 5403, 5404 and 5405. Clone 5405 was used as a coated antibody and clones 5403 and 5405 were used as biotinylated label antibodies. They were able to achieve 0.002 mIU/L analytical and 0.017 mIU/L functional sensitivity. The test had negligible cross-reactivity with LH, FSH and hCG which were tested up to 200 mIU/L and 2500 IU/L, respectively.

REFERENCES : Wu, F.-B., Han, S.-Q., and He, Y.-F. (2002) Time-resolved immunofluorometry of serum hTSH with enhanced sensitivity. J. Immunoassay & Immunochem., 23(2):191-210

Legal disclaimer

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