

## PRODUCT SPECIFICATIONS

Date: 2011-12-07

<b>PRODUCT NAME</b>	: Anti-h TSH 5404 SP-5
<b>PRODUCT SPECIFICITY</b>	: Antibody recognizes human Thyrotropin
<b>PRODUCT CODE</b>	: 100026
<b>PRODUCT BUFFER</b>	: 0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	: 36 months from manufacturing at 2-8 °C
<b>ANALYTE DESCRIPTION</b>	: 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

<b>PRODUCT APPEARANCE</b>	: Clear liquid
<b>PRODUCT CONCENTRATION</b>	: 5.0 mg/ml (+/- 10 %)
<b>PRODUCT ACTIVITY</b>	: 80-120 % compared to reference in an IFMA-test
<b>IEF-RANGE</b>	: 6.5 - 7.1
<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>	: $8.5 \times 10^5$
<b>DISSOCIATION CONSTANT</b>	: $3.9 \times 10^{-5}$
<b>AFFINITY CONSTANT</b>	: KA = $2.2 \times 10^{10}$ 1/M; KD = $4.6 \times 10^{-11}$ M (= 0.05 nM)
<b>DETERMINATION METHOD</b>	: SPR analysis (ProteOn XPR36)
<b>ANTIGEN</b>	: TSH, Scripps TO114, lot.2414402
<b>CROSS-REACTIVITIES</b>	: hCG < 0.05 % (Boehringer Cat No 253065 Lot 10774821-25/Nov 87) LH 1.0 % (Scripps Laboratories Cat No L0814 Lot 125711) FSH 1.0 % (Boehringer Cat No 252999 Lot 1483403/Jan 85)

**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
5403	5404
5404	5405, 5409

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, 21 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** :

Brockmann, E.-C., Pettersson, K., and Vehniäinen, M., (2004) Improved TSH immunoassay kinetics by using recombinant scFv antibody fragment. Poster. Univ. Turku. They compared recombinant 5404 scFv and Fab-fragments to native 5404 using 5409 as a label and their findings showed that the assay sensitivity could be improved with the use of scFv fragment. They concluded that the markedly smaller size of the recombinant fragments improves the binding capacity thus improving also the analytical sensitivity.

von Lode et al. (2003) used clones 5403 and 5404 to develop a one-step TSH assay which had 0.2 mIU/L sensitivity in a 15-min assay and 1.5 mIU/L sensitivity in 2-min assay and hence their assay is applicable for point-of-care conditions.

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** :

Eskola, J., Mäkinen, P., Oksa, L., Loikas, K., Nauma, M., Jiang, Q., Håkansson, M., Suomi, J., and Kulmala, S. (2006) Competitive immunoassay by hot electron-induced electrochemiluminescence detection and using a semiautomatic electrochemiluminometer. *J. Luminesc.*, 118:238-244

Helenius, T., and Tikanoja, S. (1986) A sensitive and practical immunoradiometric assay of thyrotropin. *Clin. Chem.* 32:514-518

von Lode, P., Hagrén, V., Palenius, T., and Lövgren, T., (2003) One-step quantitative thyrotropin assay for the detection of hypothyroidism in point-of-care conditions. *Clin. Biochem.*, 36:121-128

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

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