

PRODUCT SPECIFICATIONS

Date: 2015-02-05

PRODUCT NAME	: Anti-h TSH 5404 Fab
PRODUCT SPECIFICITY	: Antibody recognizes human Thyrotropin and the beta chain of hTSH
PRODUCT CODE	: 600020
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.
PRODUCT BUFFER	: 50 mM Na-citrate, pH 6.0; 0.9 % NaCl; 0.095 % NaN ₃ as preservative
STORAGE	: Store at 2-8 °C

PARAMETERS TESTED FROM EACH LOT

LOT NUMBER	:
MANUFACTURED	:
PRODUCT APPEARANCE	: Clear liquid
PRODUCT CONCENTRATION	: mg/ml (+/- 10 %)
PRODUCT ACTIVITY	: 80-120 % compared to reference in an IFMA test
PURITY	: ≥ 95 %

PROPERTIES OF THE CORRESPONDING MedixMAB MONOCLONAL ANTIBODY

ASSOCIATION CONSTANT	:	8.5 x 10 ⁵ 1/Ms									
DISSOCIATION CONSTANT	:	3.9 x 10 ⁻⁵ 1/s									
AFFINITY CONSTANT	:	KA = 2.2 x 10 ¹⁰ 1/M; KD = 4.6 x 10 ⁻¹¹ M (0.05 nM)									
CROSS-REACTIVITIES	:	<table> <tr> <td>hCG</td> <td><0.05 %</td> <td>(Boehringer Cat No 253065 Lot 10774821-25/Nov 87)</td> </tr> <tr> <td>LH</td> <td>1.0 %</td> <td>(Scripps Laboratories Cat No L0814 Lot 125711)</td> </tr> <tr> <td>FSH</td> <td>1.0 %</td> <td>(Boehringer Cat No 252999 Lot 1483403/Jan 85)</td> </tr> </table>	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)
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									

PAIR RECOMMENDATIONS	:	<table> <thead> <tr> <th>SOLID</th> <th>LABEL</th> </tr> </thead> <tbody> <tr> <td>5403</td> <td>5404</td> </tr> <tr> <td>5404</td> <td>5405, 5409</td> </tr> </tbody> </table>	SOLID	LABEL	5403	5404	5404	5405, 5409
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.

REFERENCES	:	<p>Brockmann, E.-C., Petterson, K., and Vehniäinen, M., (2004) Improved TSH immunoassay kinetics by using recombinant scFv antibody fragment. Poster. Univ. Turku.</p> <p>Brockmann et al. 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</p>
-------------------	---	---

fragments improves the binding capacity thus improving also the analytical sensitivity.

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

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, 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

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.

Legal disclaimer

MedixMAB monoclonal antibodies, MedixMAB Fab fragments and MedixAntigens meet their specifications if transported, stored and used according to the instructions for use. If not otherwise agreed in writing all products are sold under *General Delivery Terms*. Further information on products is available on the internet.

MedixMAB is a registered trademark of Medix Biochemica.