PRODUCT SPECIFICATIONS

Date: 2012-03-22

PRODUCT NAME	:	Anti-h LH 5303 SPRN-1
PRODUCT SPECIFICITY	:	Antibody recognizes human Luteinizing Hormone (Lutropin)
PRODUCT CODE	:	100019
PRODUCT BUFFER	:	37 mM citrate, 125 mM phosphate, 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	:	In both males and females, LH is essential for reproduction. In females FSH initiates follicular growth and at the time of the maturation of the follicle the estrogen rise leads to a release of LH over a 24-48 hour period. This 'LH surge' triggers ovulation thereby not only releasing the egg, but also initiating the conversion of the residual follicle into a corpus luteum that, in turn, produces progesterone to prepare the endometrium for a possible implantation. LH is necessary to maintain luteal function for the first two weeks. In case of a pregnancy luteal function will be further maintained by the action of hCG from the newly established pregnancy. In the male, LH acts upon the Leydig cells of the testis and is responsible for the production of testosterone.

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	:	6.3 - 7.2
PURITY	:	≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	:	IgG_1
ASSOCIATION CONSTANT	:	5.4×10^6 1/Ms
DISSOCIATION CONSTANT	:	3.4×10^{-5} 1/s
AFFINITY CONSTANT	:	KA = 1.6×10^{11} 1/M; KD = 6.3×10^{-12} M (= 6.3 pM)
DETERMINATION METHOD	:	SPR analysis (ProteOn XPR36)
ANTIGEN	:	LH, Scripps Laboratories (Cat No L0815 Lot#2360102)
CROSS-REACTIVITIES	:	LH α 9 % (Scripps Laboratories Cat No L0914 Lot 698811) LH β 10 % (Scripps Laboratories Cat No L1014 Lot 237711) FSH 1 % (Scripps Laboratories Cat No F0614 Lot 805811) hCG < 0.02 % (Scripps Laboratories Cat No C0714 Lot 191712) TSH < 0.02 % (Scripps Laboratories Cat No T0114 Lot 181711)

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EPITOPE :

EPITOPE GROUP : Beta 1 as showed in Nilsson et al. (2001)

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
5303	5301
5301	5303

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 :

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.

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

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 : In Nilsson et al. (2001) authors performed an epitope mapping analysis of 30 different monoclonal antibodies for LH. In their analysis it was shown that 5303 binds to an epitope named as beta 1. Antibodies reacting with beta 1 epitope did not react with FSH. They also showed that 5303 reacts with intact LH as well as with the beta-subunit of LH and has no cross-reactivity with hCG, TSH or FSH. Clone 5303 reacted also with the variant-LH although with slightly lower affinity.

Clone 5303 reacts also with rat LH as described in Bielmeier et al. (2004).

REFERENCES :

Bielmeier, S.R., Best, D.S. and Narotsky, M.G. (2004) Serum hormone characterization and exogenous hormone rescue of bromodichloromethane-induced pregnancy loss in the F344 rat. Toxicol. Sci. 77:101-108

Nilsson, C., Seppälä, M., and Pettersson, K., (2001) Immunological characterization of human luteinizing hormone with special regard to a common genetic variant. J.Endocrinol. 168:10-116

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