

## PRODUCT SPECIFICATIONS

Date: 2012-03-22

<b>PRODUCT NAME</b>	: Anti-h LH 5301 SP-5
<b>PRODUCT SPECIFICITY</b>	: Antibody recognizes human Luteinizing Hormone (Lutropin), and its beta-subunit
<b>PRODUCT CODE</b>	: 100016
<b>PRODUCT BUFFER</b>	: 0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	: 24 months from manufacturing at 2-8 °C
<b>ANALYTE DESCRIPTION</b>	: 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

<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>	: 6.1 - 7.0
<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>	: $5.8 \times 10^6$ 1/Ms
<b>DISSOCIATION CONSTANT</b>	: $1.3 \times 10^{-5}$ 1/s
<b>AFFINITY CONSTANT</b>	: KA = $4.4 \times 10^{11}$ 1/M; KD = $2.3 \times 10^{-12}$ M (= 2.3 pM)
<b>DETERMINATION METHOD</b>	: SPR analysis (ProteOn XPR36)
<b>ANTIGEN</b>	: LH, Scripps Laboratories (Cat No L0815 Lot#2360102)
<b>CROSS-REACTIVITIES</b>	: LH α 13 % (Scripps Laboratories Cat No L0914 Lot 698811) LH β 170 % (Scripps Laboratories Cat No L1014 Lot 237711) FSH 5 % (Scripps Laboratories Cat No F0614 Lot 805811) hCG 138 % (Scripps Laboratories Cat No C0714 Lot 210164) TSH 0.03 % (Scripps Laboratories Cat No T0114 Lot 181711)

**EPITOPE** :

**EPITOPE GROUP** : B1 in a pair wise comparison in Pettersson et al. (1991)

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
5301	5302, 5303, 5304
5302, 5303, 5304	5301

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, 7 days	N/D
+35 °C, 21 days	N/D
+45 °C, 3 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** :

In Pettersson et al. (1990) authors designed a rapid two-step procedure which had negligible cross-reactivity with TSH and FSH. In Pettersson et al. (1991) authors showed that some LH antibodies react differently with LH which is present in 25% of individuals. An assay utilizing 5301 was shown to react equally with LH of the two groups.

**REFERENCES** :

Federici, M.M., Fraser, R., Lundqvist, C., and Lankford, J.C., (1982) Production and characterization of monoclonal antibodies human lutening hormones. Fed. Proc., 41

Pettersson, K.S.I., and Söderholm J.R-M., (1990) Ultrasensitive two-site immunometric assay of human lutropin by time-resolved fluorometry. Clin. Chem. 36(11):1928-1933

Pettersson, K.S.I., and Söderholm J.R-M., (1991) Individual differences in lutropin immunoreactivity revealed by monoclonal antibodies. Clin. Chem. 37(3):333-340

Vilja, P., Wichmann, L., Isola, J., and Tuohimaa, P., (1988) Monoclonal-antibody based noncompetitive avidin-biotin assay for lutropin in urine. Clin. Chem. 34(8):1585-1590

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