

PRODUCT SPECIFICATIONS

Date: 2011-08-12

PRODUCT NAME	:	Anti-h FSH 6602 SP-5
PRODUCT SPECIFICITY	:	Antibody recognizes human Follicle Stimulating Hormone (Follitropin)
PRODUCT CODE	:	100067
PRODUCT BUFFER	:	0.9 % NaCl, 0.1 % NaN ₃ as a preservative
SHELF LIFE AND STORAGE	:	24 months from manufacturing at 2-8 °C
ANALYTE DESCRIPTION	:	Follicle-stimulating hormone (FSH) is a hormone found in humans and other animals. It is synthesized and secreted by the anterior pituitary gland. FSH regulates the development, growth, pubertal maturation, and reproductive processes of the body. In both males and females, FSH stimulates the maturation of germ cells. In females, FSH initiates follicular growth and levels then decline in the late follicular phase. This seems to be critical in selecting only the most advanced follicle to proceed to ovulation. At the end of the luteal phase, there is a slight rise in FSH that seems to be of importance to start the next ovulatory cycle.

PARAMETERS TESTED FROM EACH LOT

PRODUCT APPEARANCE	:	Clear liquid
PRODUCT CONCENTRATION	:	5.0 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	:	80-120 % compared to reference in an IFMA-test
IEF-RANGE	:	6.2 - 7.4
PURITY	:	≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	:	IgG ₁
ASSOCIATION CONSTANT	:	N/D
DISSOCIATION CONSTANT	:	N/D
AFFINITY CONSTANT	:	3 x 10 ¹⁰ l/mol
DETERMINATION METHOD	:	Radioimmunoassay (RIA)
ANTIGEN	:	FSH, Scripps Laboratories (Cat No F0614 Lot 805811)
CROSS-REACTIVITIES	:	FSH α 1 % (Scripps Laboratories Cat No F0714 Lot 734811) FSH β 68 % (Scripps Laboratories Cat No F0814 Lot 110811) LH < 0.2 % (Scripps Laboratories Cat No L0814 Lot 125711) hCG < 0.1 % (Scripps Laboratories Cat No C0714 Lot 191712) TSH < 0.1 % (Scripps Laboratories Cat No T0114 Lot 181711)

EPITOPE : N/D

EPITOPE GROUP : -

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
6602	6601

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	OK
+4 °C, 21 days	OK
+30 °C, 21 days	OK
+35 °C, 7 days	OK
+35 °C, 21 days	Failed due to reduced antigen binding
+45 °C, 3 days	OK
+45 °C, 7 days	OK, but charge changes

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 : -

REFERENCES : -

Legal disclaimer

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