

## PRODUCT SPECIFICATIONS

Date: 2014-08-04

<b>PRODUCT NAME</b>	:	Anti-hCG 5009 SP-5
<b>PRODUCT SPECIFICITY</b>	:	Antibody recognizes human Chorionic Gonadotropin
<b>PRODUCT CODE</b>	:	100008
<b>PRODUCT BUFFER</b>	:	0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	:	18 months from manufacturing at 2-8 °C
<b>ANALYTE DESCRIPTION</b>	:	Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced in pregnancy by the developing embryo soon after conception and later by the syncytiotrophoblast (part of the placenta). Its role is to prevent the disintegration of the corpus luteum of the ovary and thereby maintain progesterone production that is critical for a pregnancy in humans. Early pregnancy testing, in general, is based on the detection of hCG. hCG is produced also by some tumors, but it is not known whether this production is a contributing cause or an effect of tumorigenesis.

## 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>	:	6.0 - 6.7
<b>PURITY</b>	:	≥ 95 %

## PARAMETERS DETERMINED ONLY DURING PRODUCT R&amp;D PHASE

<b>CLASS AND SUBCLASS</b>	:	IgG <sub>1</sub>
<b>ASSOCIATION CONSTANT</b>	:	1.1 x 10 <sup>6</sup>
<b>DISSOCIATION CONSTANT</b>	:	3.1 x 10 <sup>-4</sup>
<b>AFFINITY CONSTANT</b>	:	K <sub>A</sub> = 3.6 x 10 <sup>9</sup> 1/M; K <sub>D</sub> = 2.8 x 10 <sup>-10</sup> M (= 0.28 nM)
<b>DETERMINATION METHOD</b>	:	SPR analysis (ProteOn XPR36)
<b>ANTIGEN</b>	:	hCG (Scripps CO714 lot.2430801)
<b>CROSS-REACTIVITIES</b>	:	LH (K <sub>D</sub> = 1.2 nM) No cross reactivity with hCG α, hCG β, FSH, TSH

**EPITOPE** : C-2 as described in Berger et.al. (2013)

Two antibodies binding to the same, or closely located epitopes cannot be used as a pair in a sandwich assay.

PAIR RECOMMENDATIONS	SOLID	LABEL
	5009	5006, 5014
	5014	5009
	5009	6601 ( $\alpha\beta$ -pair)

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
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.	-70 °C, 21 days	OK
	-20 °C, 21 days	OK
	+4 °C, 21 days	OK
	+25 °C, 21 days	OK
	+35 °C, 21 days	OK
	+45 °C, 7 days	OK

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.

**MISCELLANEOUS** : -

**REFERENCES** : Berger, P., Paus, E., Hemken, P.M., Sturgeon, C., Stewart, W.W., Skinner, J.P., Harwick, L.C., Saldana, S.C., Ramsay, C.S., Rupprecht, K.R., Olsen, K.H., Bidart, J.M. and Stenman, U.H. (2013) Candidate epitopes for measurement of hCG and related molecules: the second ISOBM TD-7 workshop. *Tumor Biol.*, 34: 4033-4057.

### Legal disclaimer

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