

PRODUCT SPECIFICATIONS

Date: 2014-08-04

PRODUCT NAME	: Anti-h CGbeta 5012 SPRN-1
PRODUCT SPECIFICITY	: Antibody recognizes human Chorionic Gonadotropin free beta chain and its core fragment
PRODUCT CODE	: 100010
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	: 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

PRODUCT APPEARANCE	: Clear liquid
PRODUCT CONCENTRATION	: 1.00 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	: 80-120 % compared to reference in an IFMA-test
IEF-RANGE	: 5.5 - 6.7
PURITY	: ≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	: IgG ₁
ASSOCIATION CONSTANT	: 2.1×10^4
DISSOCIATION CONSTANT	: 1.7×10^{-4}
AFFINITY CONSTANT	: $K_A = 1.2 \times 10^9$ 1/M; $K_D = 8.1 \times 10^{-10}$ M (= 0.81 nM)
DETERMINATION METHOD	: SPR analysis (ProteOn XPR36)
ANTIGEN	: hCG-beta (Scripps CO914 lot.2310001)
CROSS-REACTIVITIES	: No cross-reactivity with Intact hCG, hCG- α -subunit, LH, FSH, TSH, LH- β -subunit, FSH- β -subunit, TSH- β -subunit

EPITOPE : Beta-7 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
	5012	5004, 5006, 5008, 5014
	5004	5012

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	N/D
	-20 °C, 21 days	OK
	+4 °C, 21 days	OK
	+30 °C, 21 days	OK
	+35 °C, 21 days	OK
	+45 °C, 3 days	OK
	+45 °C, 7 days	Failed due to reduced antigen binding

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 : Clone 5012 binds to free- β -subunit and hCG β -core fragment. Binding of 5012 to intact hCG is sterically hindered by the α -subunit and therefore assays developed with 5012 do not measure intact hCG.

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

MedixMAB monoclonal antibodies meet their specifications if transported, stored and used according to the instructions for use. See also separate *Notes on use and storage of monoclonal antibodies*. If not otherwise agreed in writing all products are sold under *General Delivery Terms*. Other terms may apply if MedixMAB monoclonal antibodies are purchased from an official distributor of Medix Biochemica products. MedixMAB is a registered trademark of Medix Biochemica and may not be used or reproduced without Medix Biochemica's written permission. Further information on products and methods is available from medixMAB website and extranet.