

PRODUCT SPECIFICATIONS

Date: 2011-08-12

PRODUCT NAME	: Anti-h PSA 8301 SPRN-5
PRODUCT SPECIFICITY	: Antibody recognizes human Prostate-Specific Antigen
PRODUCT CODE	: 100102
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	: Prostate-specific antigen (PSA) is a protein produced by the cells of the prostate gland. PSA is present in small quantities in the serum of normal men, and is often elevated in the presence of prostate cancer and in other prostate disorders. A blood test to measure PSA is considered the most effective test currently available for the early detection of prostate cancer, but this effectiveness has also been questioned.

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	: 5.7 - 7.0
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	: 1 x 10 ¹¹ l/mol
DETERMINATION METHOD	: Radioimmunoassay (RIA)
ANTIGEN	: PSA, Aalto (Cat No AJ 3036, Lot 1133)
CROSS-REACTIVITIES	: PSA/α ₁ -ACT complex 59 % (Scripps Laboratories Cat No P0624 Lot 777464) Kallikrein < 0.04 % (Biodesign Cat No P0514 Lot 191K) PAP < 0.04 % (Scripps Laboratories Cat No P0514 Lot 534164 A)

EPITOPE : Residues 158-163 (Rye et al., 1999).

EPITOPE GROUP : Group 3a (Rye et al., 1999).

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
8301	8311
8301	8312

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, 21 days	OK
+45 °C, 7 days	OK

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 : Clone 8301 reacts with non-reduced and reduced intact PSA but not with reduced PSA fragments (Rye et al., 1999). In the same study affinities for free-PSA and PSA-ACT-complex were, 9.0×10^{-9} mol/l and 5.2×10^{-9} , respectively. They also noted that antibodies binding to epitope group 3a form a good pair with antibodies from groups 1, 5a, 5c and 6. Clone 8301 does not cross-react with human kallikrein-2 (Black, 1999b)

REFERENCES : Black, M.H., Grass, C.L., Leinonen, J., Stenman, U-H., and Diamandis, E.P., (1999a) Characterization of monoclonal antibodies for prostate-specific antigen and development of highly sensitive free prostate-specific antigen assays. Clin. Chem. 45(3):347-354

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Magklara, A., Scorilas, A., López-Otín, C., Vizoso, F., Ruibal, A., and Diamandis, E.P., (1999) Human glandular kallikrein in breast milk, amniotic fluid, and breast cyst fluid. Clin. Chem., 45(10):1774-1780

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Rye, P.D., Borner, O.P., and Paus, E. (guest editors) (1999), ISOBM TD-3 International Workshop on monoclonal antibodies against prostate-specific antigen. Tumor Biol., 20(suppl 1):1-94

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