

## PRODUCT SPECIFICATIONS

Date: 2011-08-12

<b>PRODUCT NAME</b>	: Anti-h PSA 8312 SPRN-5
<b>PRODUCT SPECIFICITY</b>	: Antibody recognizes human Prostate-Specific Antigen
<b>PRODUCT CODE</b>	: 100139
<b>PRODUCT BUFFER</b>	: 37 mM citrate, 125 mM phosphate, pH 6.0, 0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	: 36 months from manufacturing at 2-8 °C
<b>ANALYTE DESCRIPTION</b>	: 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

<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>	: 5.9 - 6.6
<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>	: N/D
<b>DISSOCIATION CONSTANT</b>	: N/D
<b>AFFINITY CONSTANT</b>	: 3 x 10 <sup>9</sup> l/mol
<b>DETERMINATION METHOD</b>	: SPR analysis (Biacore)
<b>ANTIGEN</b>	: PSA, Scripps (P0725, Lot 2206902)
<b>CROSS-REACTIVITIES</b>	: PSA/α <sub>1</sub> -ACT complex 15 % Human-Kallikrein-2 no cross-reactivity PAP no cross-reactivity

**EPITOPE** : Residues 3-11 (Rye et al., 1999).

**EPITOPE GROUP** : Group 6a (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	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	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

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	OK
6.0	OK
7.0	OK
8.0	OK

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 8312 reacts with non-reduced and reduced intact PSA as well as with reduced PSA fragments (Rye et al., 1999). In the same study affinities for free-PSA and PSA-ACT-complex were,  $7.5 \times 10^{-9}$  mol/l and  $1.03 \times 10^{-10}$ , respectively. They also noted that antibodies binding to epitope group 6 form a good pair with antibodies from groups 1 and 3. Clone 8312 cross-reacts with human kallikrein-2 (Rye, 1999a). Clone 8312 was coded as 5E4 in (Rye et al. 1999).

**REFERENCES** : 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

#### Legal disclaimer

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