

## PRODUCT SPECIFICATIONS

<b>Name</b>	Anti-h PSA 8311 SPRN-1
<b>Specificity</b>	Antibody recognizes human prostate-specific antigen
<b>Description</b>	Monoclonal mouse antibody, cultured <i>in vitro</i> under conditions free from animal-derived components
<b>Product code</b>	100103
<b>Product buffer solution</b>	37 mM citrate, 125 mM phosphate, pH 6.0, 0.9 % NaCl, 0.095 % 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 healthy 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 ON EACH LOT

<b>Product appearance</b>	Liquid, may turn slightly opaque during storage
<b>Product concentration</b>	1.0 – 1.1 mg/ml
<b>Immunoreactivity</b>	80–120 % compared to the reference sample in an FIA test
<b>IEF Profile</b>	6.8 - 7.5
<b>Purity</b>	≥ 95 %

## PARAMETERS DETERMINED DURING PRODUCT DEVELOPMENT

<b>Subclass</b>	IgG <sub>2a</sub>
<b>Association rate constant</b>	Not determined (N/D)
<b>Dissociation rate constant</b>	N/D
<b>Affinity constant</b>	1 × 10 <sup>10</sup> l/mol
<b>Determination method</b>	Radioimmunoassay (RIA)
<b>Determination antigen</b>	PSA, Aalto (Cat AJ 3036, Lot 1133)

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### Oy Medix Biochemica Ab

**Headquarters and manufacturing**  
Klovinpellontie 3  
FI-02180 Espoo, Finland

medix@medixbiochemica.com  
www.medixbiochemica.com  
VAT reg. no. FI4631532

### Cross-reactivities

PSA/ $\alpha$ 1-ACT complex 76 % (Scripps Laboratories, Cat P0624, Lot 777464)  
 Kallikrein < 0.36 % (Biosdesign, Cat P0514, Lot 191K)  
 PAP < 0.36 % (Scripps Laboratories, Cat P0514, Lot 534164 A)

### Epitope

Residues 3-11, group 6a as described in Rye et al. (1999)

### Pair recommendations

		DETECTION			
		8301	8311	8312	8313 (free PSA)
CAPTURE	8301	-	+	+	+
	8311	+	-	-	+
	8312	+	-	-	+
	8313 (free PSA)	+	+	+	-

Please note that pair recommendations are based on results obtained by our laboratory. Equally good results may be obtained using other pairs and therefore these recommendations are only indicative.

### Product stability

TEMPERATURE, TIME	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

Stability testing is performed in the product buffer to see whether different temperatures affect the antigen binding, charge or composition of the antibody. Please note that the shelf life given on the first page is based on real time stability testing at 2-8 °C in the product buffer.

### Miscellaneous

Antibody recognizes native PSA antigen, Lee Biosolutions 497-11 and 497-17, and native PSA-ACT complex, Lee Biosolutions 498-11.

Clone 8311 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,  $1.7 \times 10^{-10}$  mol/l and  $1.55 \times 10^{-10}$ , respectively. They also noted that antibodies binding to epitope group 6 form a good pair with antibodies from groups 1 and 3. Clone 8311 cross-reacts with human kallikrein-2 (Black, 1999b) and can be used to develop a hK2-assay.

### 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
- Black, M.H., Magklara, A., Obiezu, C.V., Melegos, D.N. and Diamandis, E.P., (1999b) Development of an ultrasensitive immunoassay for human glandular kallikrein with no cross-reactivity from prostate-specific antigen. *Clin. Chem.*, 45(6):790-799
- Ferguson, R.A., Yu, H., Kalyvas, M., Zammit, S. and Diamandis, E.P., (1996) Ultrasensitive detection of prostate-specific antigen by time-resolved immunofluorometric assay and the Immulite® immunochemiluminescent third-generation assay: potential applications in prostate and breast cancer. *Clin. Chem.*, 42(5):675-684
- 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
- Obiezu, C.V., Giltay, E.J., Magklara, A., Scorilas, A., Gooren, L.J.G., Yu, H., Howarth, D.J.C. and Diamandis, E.P., (2000) Serum and urinary prostate-specific antigen and urinary human glandular kallikrein concentrations are significantly increased after testosterone administration in female-to-male transsexuals. *Clin. Chem.*, 46(6):859-862
- 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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