

## PRODUCT SPECIFICATIONS

Date: 2011-08-12

<b>PRODUCT NAME</b>	: Anti-h AFP 5108 SP-5
<b>PRODUCT SPECIFICITY</b>	: Antibody recognizes human Alpha <sub>1</sub> -Fetoprotein
<b>PRODUCT CODE</b>	: 100015
<b>PRODUCT BUFFER</b>	: 0.9 % NaCl, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	: 24 months from manufacturing at 2-8 °C
<b>ANALYTE DESCRIPTION</b>	: Alpha-fetoprotein (AFP, α-fetoprotein) is a major plasma protein produced by the yolk sac and the liver during fetal life. The protein is thought to be the fetal counterpart of serum albumin. In humans, AFP levels decrease gradually after birth, reaching adult levels by 8 to 12 months. Normal adult AFP levels are low, but detectable; however, AFP has no known function in healthy adults. In normal fetuses, AFP binds the hormone estradiol. AFP is measured in pregnant women, using maternal blood or amniotic fluid, as a screening test for a subset developmental abnormalities: it is principally increased in open neural tube defects and omphalocele & decreased in Down syndrome. It is also measured in pregnant women, other adults, and children, serving as a biomarker to detect a subset of tumors, principally hepatocellular carcinoma and endodermal sinus tumors.

### 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>	: 6.5 - 7.2
<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>10</sup> l/mol
<b>DETERMINATION METHOD</b>	: Radioimmunoassay (RIA)
<b>ANTIGEN</b>	: AFP, DAKO (Cat No X557 Lot 13C)
<b>CROSS-REACTIVITIES</b>	: Antibody AFP does not cross-react with human albumin. Others not tested.

**EPITOPE** : N/D

**EPITOPE GROUP** : -

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
5107	5108

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	N/D
+4 °C, 21 days	N/D
+25 °C, 21 days	N/D
+35 °C, 7 days	N/D
+35 °C, 21 days	N/D
+45 °C, 3 days	N/D
+45 °C, 7 days	N/D

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** : Authors in Koskinen et al. (2005) developed a dry- and wet-chemistry based assay methods for AFP with detection limits of 0.41 ng/mL and 0.67 ng/mL, respectively.

**REFERENCES** : Koskinen, J.O., Meltola, N.J., Soini, E. and Soini, A.E. (2005) A lab-on-a-chip compatible bioaffinity assay method for human  $\alpha$ -fetoprotein. *Lab Chip*, 5:1408-1411

Stenman, U.-H., Sutinen, M.-L., Selander, R.-K., Tontti, K., and Schröder, J., (1981) Characterization of a monoclonal antibody to human alpha-fetoprotein and its use in affinity chromatography. *J. Immunol. Meth.*, 46:337-345

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