

**PRODUCT SPECIFICATIONS**

Date: 2011-08-12

<b>PRODUCT NAME</b>	:	Anti-h D-Dimer 1402 SPTNZ-5
<b>PRODUCT SPECIFICITY</b>	:	Antibody recognizes human D-Dimer
<b>PRODUCT CODE</b>	:	100205
<b>PRODUCT BUFFER</b>	:	50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.05 % Sulfbetaine, 0.1 % NaN <sub>3</sub> as a preservative
<b>SHELF LIFE AND STORAGE</b>	:	Shelf life 12 months at +2-8 °C
<b>ANALYTE DESCRIPTION</b>	:	D-Dimer (DD) is fibrin degradation product created during fibrinolysis when plasmin degrades the fibrin clot. Pulmonary embolism (PE) is challenging diagnosis because most lung scans are inconclusive and pulmonary angiography is an invasive procedure associated with complications. About 70% of PE are precipitated by deep vein thrombosis (DVT). The DD test is extremely helpful in excluding PE. DD is more sensitive for the diagnosis of proximal DVT than for the diagnosis of distal DVT. DD is also valuable for monitoring patients during and after anticoagulant treatment for recurrent DVT.

**PARAMETERS TESTED FROM EACH LOT**

<b>PRODUCT APPEARANCE</b>	:	Clear liquid, may turn opaque during storage
<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>	:	Does not form focusing bands
<b>PURITY</b>	:	≥ 95 %

**PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE**

<b>CLASS AND SUBCLASS</b>	:	IgG <sub>2b</sub>
<b>ASSOCIATION CONSTANT</b>	:	1 x 10 <sup>5</sup> 1/Ms
<b>DISSOCIATION CONSTANT</b>	:	Could not be measured
<b>AFFINITY CONSTANT</b>	:	N/D
<b>DETERMINATION METHOD</b>	:	-
<b>ANTIGEN</b>	:	-
<b>CROSS-REACTIVITIES</b>	:	Cross-reacts with human fibrinogen

**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
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1401	1402
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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
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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	OK
-20 °C, 21 days	OK
+4 °C, 21 days	OK
+25 °C, 21 days	OK
+35 °C, 21 days	OK
+45 °C, 3 days	OK
+45 °C, 7 days	Failed due to precipitation

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
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5.0	OK
6.0	OK
7.0	OK
8.0	OK, but charge changes

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** :

The specificity increases in higher temperatures.

**REFERENCES** : -

**Legal disclaimer**

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