

PRODUCT SPECIFICATIONS

Date: 2011-08-12

PRODUCT NAME	:	Anti-h D-Dimer 1401 SPTN-5
PRODUCT SPECIFICITY	:	Antibody recognizes human D-Dimer
PRODUCT CODE	:	100204
PRODUCT BUFFER	:	50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.1 % NaN ₃ as a preservative
SHELF LIFE AND STORAGE	:	6 months at 2-8 °C
ANALYTE DESCRIPTION	:	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

PRODUCT APPEARANCE	:	Clear liquid, may turn slightly opaque during storage
PRODUCT CONCENTRATION	:	5.0 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	:	80-120 % compared to reference in an IFMA-test
IEF-RANGE	:	6.3 – 8.4
PURITY	:	≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	:	IgG ₃
ASSOCIATION CONSTANT	:	9 x 10 ⁴ 1/Ms
DISSOCIATION CONSTANT	:	Could not be measured
AFFINITY CONSTANT	:	N/A
DETERMINATION METHOD	:	SPR analysis (ProteOn XPR36)
ANTIGEN	:	FDP-D-Dimer, Chrystal Chem Inc., Lot SDD-1
CROSS-REACTIVITIES	:	No cross-reactivity against human Fibrinogen, 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
1401	1402, 1403

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, 3 days	OK
+45 °C, 7 days	Failed due to aggregation

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 : -

REFERENCES : -

Legal disclaimer

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