

PRODUCT SPECIFICATIONS

Date: 2011-08-12

PRODUCT NAME	:	Anti-h CYFRA21-1 1604 SPTN-5
PRODUCT SPECIFICITY	:	Antibody recognizes human CYFRA21-1 fragment of Cytokeratin 19
PRODUCT CODE	:	100222
PRODUCT BUFFER	:	50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.1 % NaN ₃ as a preservative
SHELF LIFE AND STORAGE	:	12 months at 2-8 °C
ANALYTE DESCRIPTION	:	CYFRA21-1 is a fragment of Cytokeratin 19 which is expressed in various types of epithelial cells and tumor cells of epithelial origin. Serum CYFRA21-1 has been used as a tumor marker of different origins and especially in non-small cell lung cancer.

PARAMETERS TESTED FROM EACH LOT

PRODUCT APPEARANCE	:	Clear liquid, may turn opaque during storage
PRODUCT CONCENTRATION	:	5.0 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	:	80 – 120 % compared to reference in an IFMA-test
IEF-RANGE	:	7.0 – 8.2
PURITY	:	≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	:	IgG _{2a}
ASSOCIATION CONSTANT	:	3×10^4 1/Ms
DISSOCIATION CONSTANT	:	6×10^{-5} 1/s
AFFINITY CONSTANT	:	$K_A = 5 \times 10^8$ 1/M, $K_D = 2 \times 10^{-9}$ M
DETERMINATION METHOD	:	SPR analysis (ProteOn XPR36)
ANTIGEN	:	Recombinant human Cytokeratin 19 (Biodesign cat# A44214H, lot# 12F15608)
CROSS-REACTIVITIES	:	100 % Cytokeratin 19

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
	1604	1603
	1603	1604

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
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, 7 days	OK
	+35 °C, 21 days	OK, but charge changes
	+45 °C, 3 days	OK, but charge changes
	+45 °C, 7 days	Failed due to reduced antigen binding

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 : -

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