PRODUCT SPECIFICATIONS

Date: 2014-01-17

PRODUCT NAME	:	Anti-h CEA 5909 SP-5
PRODUCT SPECIFICITY	:	Antibody recognizes human Carcinoembryonic Antigen
PRODUCT CODE	:	100428
PRODUCT BUFFER	:	0.9 % NaCl, 0.1 % NaN_3 as a preservative
SHELF LIFE AND STORAGE	:	36 months from manufacturing at 2-8 °C
ANALYTE DESCRIPTION	:	Carcinoembryonic antigen (CEA) is a glycoprotein involved in cell adhesion. It is normally produced during fetal development, but the production of CEA stops before birth. Therefore, it is not usually present in the blood of healthy adults, but elevated levels have been found in individuals with carcinomas. CEA measurement is mainly used as a tumor marker to identify recurrences after surgical resection. CEA levels may also be raised in some non-neoplastic conditions like ulcerative colitis, pancreatitis and cirrhosis.

PARAMETERS TESTED FROM EACH LOT

PRODUCT APPEARANCE	:	Clear liquid. May precipitate during storage which does not alter the product specifications. Precipitate can be removed by centrifugation or filtering
PRODUCT CONCENTRATION	:	5.0 mg/ml (+/- 10 %)
PRODUCT ACTIVITY	:	80-120 % compared to reference in an IFMA-test
IEF-RANGE	:	5.8 - 6.4
PURITY	:	≥ 95 %

PARAMETERS DETERMINED ONLY DURING PRODUCT R&D PHASE

CLASS AND SUBCLASS	:	IgG_1
ASSOCIATION CONSTANT	:	N/D
DISSOCIATION CONSTANT	:	N/D
AFFINITY CONSTANT	:	3×10^{10} l/mol
DETERMINATION METHOD	:	Radioimmunoassay (RIA)
ANTIGEN	:	CEA, BIOSCAN (Cat No 100 Lot 118-1A)
CROSS-REACTIVITIES	:	No cross-reactivity with human NCA, NCA-2 or BGPI (biliary glycoprotein-1).

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EPITOPE : N/D

EPITOPE GROUP : Epitope group C (Bhayana et al., 1989)

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
5909	5905
5909	5910

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 :

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.

TEMPERATURE, DAYS	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	Failed due to reduced antigen binding
+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.

MISCELLANEOUS : In Bhayana et al. (1989) authors made an epitope mapping for 11 monoclonal antibodies from Medix Biochemica and they found that the antibodies bound to 5 different epitope groups (A to F) and 5909 was found to bind to epitope group C.

REFERENCES :

Bhayana, V., and Diamandis, E.P., (1989) A double monoclonal time-resolved immunofluorometric assay of carcinoembryonic antigen is serum. Clin. Biochem., 22:433-438

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