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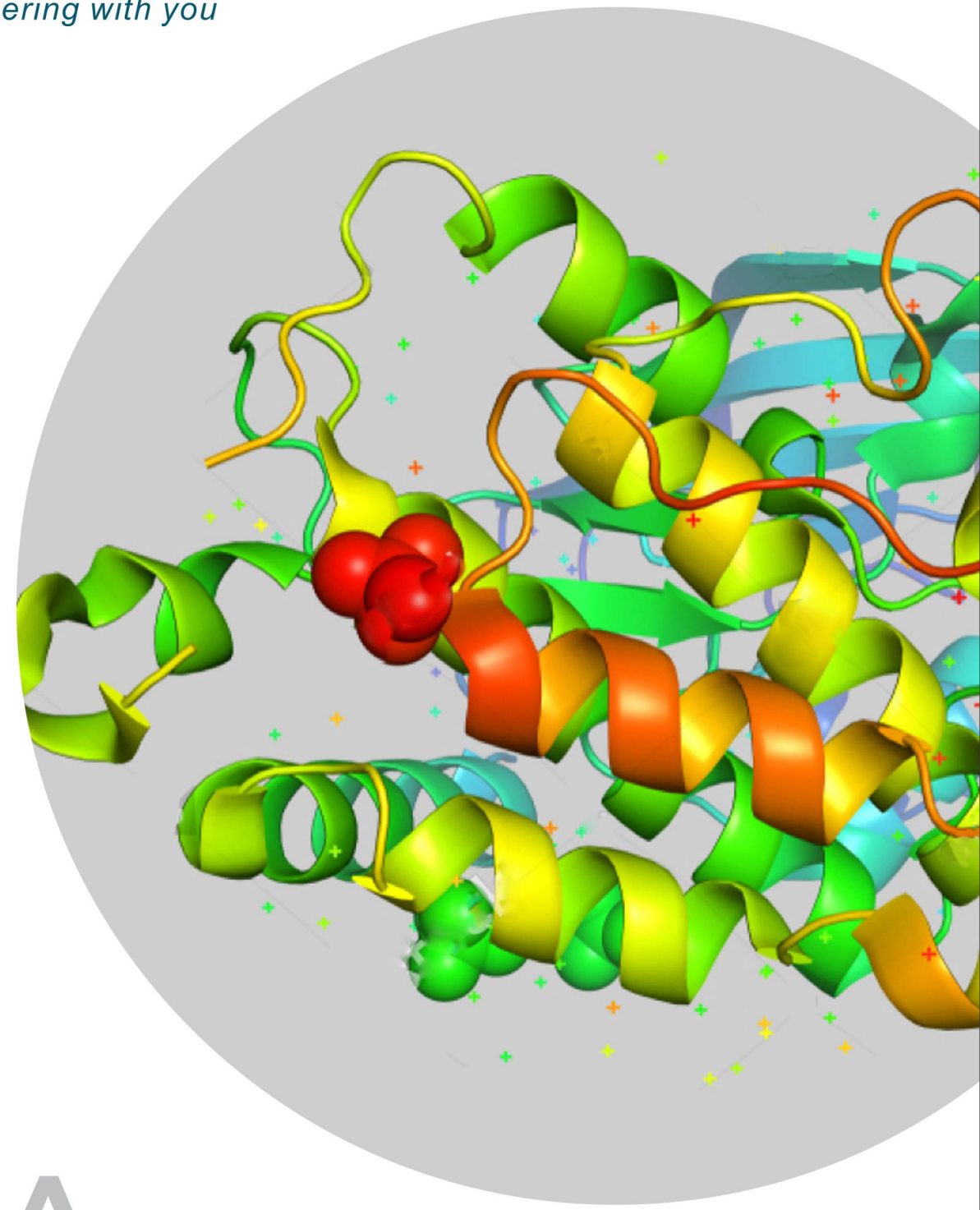

CAg

CANCER MARKERS

Carbohydrate Antigen CA 19-9 (Partially pure)

DESCRIPTION

Gastrointestinal tumor antigen is a large glycoprotein defined by a carbohydrate epitope, Cancer Antigen 19-9 (CA 19-9), located on a protein core mucin. CA19-9 is the sialylated form of Lewis Antigen. CA 19-9 is a tumor marker elevated in blood of patients with carcinoma of the gastro-intestinal tract. Elevations of this biomarker are observed in many types of gastrointestinal cancer, such as colorectal cancer, pancreatic cancer, esophageal cancer and hepatocellular carcinoma. Healthy people can have small amounts of CA 19-9 in their blood. High levels of CA 19-9 display signs of pancreatic cancer, but sometimes high levels of CA 19-9 can indicate other types of cancer or certain noncancerous disorders, including cirrhosis and gallstones.

APPLICATION

- Carbohydrate Antigen CA 19-9 (Partially Pure) is used for the manufacturing of positive controls for ELISA and ECLIA based immunoassays for Gastric-related Cancer.
- CA 19-9 is often used as Life Science Research Material in cancer research.

SPECIFICATION

Test Parameters	Acceptance Criteria
Physical Appearance	Clear Protein Solution
CA 19.9 Concentration	≥ 70,000 IU/ml (CLIA Method)
Shelf life	3 years
Buffer details	Tris-50mM at pH 7.4 ± 0.2 containing NaCl- 150mM and NaN_3 -15mM
Purity	Specific Protein to Total protein should be ≥ 10000 IU/ml/OD
Cross Contaminants	CA 125, CA 15.3 concentrations should be ≤ 20% of CA 19.9 concentration
Cross Contaminants CEA	For information
Cross Contaminants AFP	For information
Cross Contaminants Transferrin	For information
Anti HIV 1&2	Negative (ELISA Assay)
Anti HCV	Negative (ELISA Assay)
HBsAg Antigen	Negative (ELISA Assay)
HBV DNA	Not Detected (PCR Analysis)
HIV DNA	Not Detected (PCR Analysis)
HCV RNA	Not Detected (PCR Analysis)
Storage conditions	2 to 8° C

REFERENCES

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- K.S. Goonetilleke, A.K. Siriwardena. Systematic review of carbohydrate antigen (CA19-9) as a biochemical marker in the diagnosis of pancreatic cancer. Eur. J. Surg. Oncol. 33 (2007) 266-270.

Breast Cancer Antigen CA 15-3 (Partially pure)

DESCRIPTION

Carcinoma Antigen CA 15-3 is a tumor marker for many types of cancer, most notably breast cancer. Elevated CA15-3, in conjunction with alkaline phosphatase, is found to be associated with an increased chance of early recurrence in breast cancer. CA15-3 (MUC-1) is expressed by most simple epithelial cells, and its expression is upregulated in the breast during pregnancy and lactation. It is secreted by the surface epithelia of cancer tissues and shed in to the blood stream. The main application for measurement of CA15-3 has been shown to monitor disease progression for patients with breast cancer, to detect distant tumor metastasis. Serial testing can assist in early detection of disease recurrence in previously treated stage II and III breast cancer patients. Free floating CA 15-3 at high level is detected in the blood of breast cancer patients.

APPLICATION

- Breast Cancer Antigen (CA 15-3) Partially Pure is used for the manufacturing of positive controls for ELISA and ECLIA based immunoassays for Breast Cancer.
- CA 15-3 can also be used as Life Science Research Material in cancer research.

SPECIFICATION

Test Parameters	Acceptance Criteria
Physical Appearance	Clear Protein Solution
CA 15.3 Concentration	≥ 5000 IU/ml (ECLIA by Roche Cobas)
Shelf life	3 years
Buffer details	50 mM Phosphate buffer, 150 mM NaC1, 0.1 Sodium Azide, pH 7.4 ± 0.2
Purity	Activity / mL / OD 280 nm
Cross Contaminants	CA 125,CA 19.9, CA 72-4, CEA, AFP, and Ferritin concentrations should be ≤ 25% of CA 15.3 concentration (ECLIA by Roche Cobas
Anti HIV 1&2	Negative (ELISA Assay)
Anti HCV	Negative (ELISA Assay)
HBsAg Antigen	Negative (ELISA Assay)
HBV DNA	Not Detected (PCR Analysis)
HIV DNA	Not Detected (PCR Analysis)
HCV RNA	Not Detected (PCR Analysis)
Storage conditions	2 to 8° C

REFERENCES

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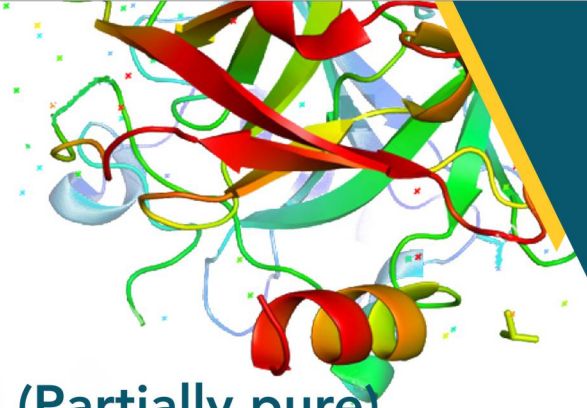
- S. Chourin, D. Georgescu , C. Gray, C. Guillemet, A. Loeb, C. Veyret, J.P. Basuyau, Value of CA 15-3 determination in the initial management of breast cancer patients. Annals of Oncology, 20 (2009) 962-964.



INFECTIOUS DISEASE

Cancer Antigen CA 125 (Partially pure)

DESCRIPTION

In serum, Cancer Antigen 125 (CA125) is associated with a high molecular weight glycoprotein. CA125 is a surface antigen associated with epithelial ovarian cancer. Ovarian cancer is the second most common cancer of the reproductive organs observed globally in women. CA-125 has found application as a tumor marker or biomarker that may be elevated in the blood of some patients with specific types of cancers, or other conditions that are benign. American Congress of Obstetricians and Gynecologists recommend that women with an average risk of ovarian cancer to undergo routine CA-125 screening and/or other screening tests for this cancer type. Around 90% of women with advanced ovarian cancer have elevated levels of CA-125 in their blood serum, making CA-125 a useful tool for detecting ovarian cancer after the onset of symptoms. Also, monitoring CA-125 blood serum levels is useful for determining how ovarian cancer is responding to treatment and for predicting a patient's prognosis after treatment

APPLICATION

- Cancer Antigen CA 125 Partially Pure is used for manufacturing of positive controls for ELISA and ECLIA based immunoassays for Ovarian Cancer.
- CA 125 is used as Life Science Research Material in cancer research.

SPECIFICATION

Test Parameters	Acceptance Criteria
Physical Appearance	Clear Protein Solution
CA 125 Concentration	≥ 70,000 IU/ml (CLIA Method)
Shelf life	3 years
Buffer details	Tris-25mM at pH 7.4 ± 0.2 containing NaCl- 150mM and NaN_3 -15mM
Purity	Specific Protein to Total protein should be ≥ 10,000 IU/ml/OD
Cross Contaminants	CA 15.3, CA 19.9 concentrations should be ≤ 20% of CA 125 concentration
Cross Contaminant CEA	For information
Cross Contaminant AFP	For information
Cross Contaminant Transferrin	For information
Anti HIV 1&2	Negative (ELISA Assay)
Anti HCV	Negative (ELISA Assay)
HBsAg Antigen	Negative (ELISA Assay)
HBV DNA	Not Detected (PCR Analysis)
HIV DNA	Not Detected (PCR Analysis)
HCV RNA	Not Detected (PCR Analysis)
Storage conditions	2 to 8° C

REFERENCES

- N. Osman, N. O'Leary, E. Mulcahy, N. Barrett, F. Wallis, K. Hickey, R. Gupta, Correlation of serum CA125 with stage, grade and survival of patients with epithelial ovarian cancer at a single centre. Irish Medical Journal 101 (2008) 245-247.
- M. Boivin, D. Lane, A. Piché, C. Rancourt, CA125 (MUC16) tumor antigen selectively modulates the sensitivity of ovarian cancer cells to genotoxic drug-induced apoptosis. Gynecologic Oncology. 115 (2009) 407-413.

Alpha-fetoprotein (High pure)

DESCRIPTION

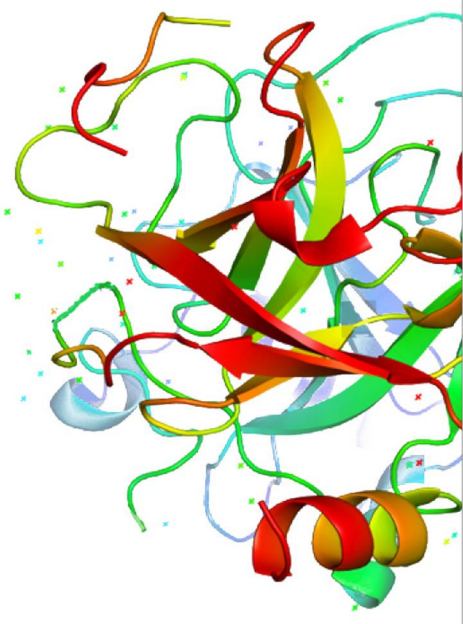
Alpha-fetoprotein (AFP) is a major plasma protein produced by the yolk sac and the fetal liver during fetal development. AFP is a glycoprotein of 591 amino acids and a carbohydrate moiety. Alpha-fetoprotein is found in monomeric as well as dimeric and trimeric forms binding copper, nickel, fatty acids and bilirubin. AFP measurement is used to detect certain abnormalities during pregnancy. If elevated levels are found in amniotic fluids, it can indicate a developmental defect in the fetus.. It is a valuable diagnostic tumor marker. Also, elevated level of AFP correlates with the presence of hepatocellular carcinoma (HCC). Levels of serum AFP are widely used for HCC screening in patients with chronic liver disease.

APPLICATION

- Alpha-fetoprotein High Pure is used for the manufacturing of AFP controls
- It is used as calibrators for Latex and ELISA based AFP diagnostic kits and other clinical and biosensor based products.
- AFP is also used as a Life Science Research Material

SPECIFICATION

Test Parameters	Acceptance Criteria
Physical Appearance	Clear to Straw yellow Solution
AFP Concentration	Range 0.9 to 2.0 mg/ml
OD at 280 nm	Range 0.9 to 2.0 mg/ml
Shelf life	3 years
Buffer details	Tris-25mM at pH 7.5 ± 0.2 containing NaCl- 150mM and NaN_3 -15mM 5% Sucrose and 15mM NaN_3
% Purity	≥ 99%
SDS PAGE	Band corresponding to Mol. Wt. of 60 to 65 kDa
Anti HIV 1&2	Negative (ELISA Assay)
Anti HCV	Negative (ELISA Assay)
HBsAg Antigen	Negative (ELISA Assay)
HBV DNA	Not Detected (PCR Analysis)
HIV DNA	Not Detected (PCR Analysis)
HCV RNA	Not Detected (PCR Analysis)
Storage conditions	2 to 8° C



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