D. In vitro, RIA

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CLINICAL USEFULNESS OF PROLIFIGEN TPA RIA KIT "DAICHI"
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Tissue polypeptide antigen (TPA) is a tumor marker, purified from 56 mixed malignant tumors. Recently new RIA kit for measuring serum TPA values was developed. In order to determine the upper limits of normal values and to evaluate the clinical usefulness of measuring serum TPA values in cancer patients, cooperative study was carried out in 17 institutes. More than 95 % of 823 normal controls showed serum TPA values of below 110 U/L and cut-off values was determined as 110 U/L. Serum TPA was positive in 63.1 % (260/411) for lung cancer, 28.9 % (28/79) for breast cancer, 51.0 % (134/263) for stomach cancer, 62.6 % (93/150) for colon cancer, 89.4 % (141/161) for hepatoma, 69.7 % (451/66) for pancreatic cancer, 69.7 % (45/63) for bladder cancer and 64.3 % (46/71) for prostatic cancer, respectively. In lung cancer, serum TPA values were related to the stage of the disease but there was no difference among the histological classifications. However in many (66.3 %) patients with benign diseases, serum TPA concentrations were below 110 U/L, except in acute and chronic hepatitis and urological diseases. Furthermore, measurement of serum TPA concentration was useful in the monitoring of cancer patients.

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BASIC AND CLINICAL EVALUATION OF SQUAMOUS CELL CARCINOMA RELATED ANTIGEN (SCC) RIA KIT
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Serum concentrations of squamous cell carcinoma related antigen (SCC) were measured using RIA kit provided by DAINABOT. Basic characteristics of the kit and clinical usefulness were evaluated. Basic evaluation was performed on standard curve, intraassay, interassay, dilution and recovery test. Almost satisfactory results were obtained. In clinical evaluation, we have measured serum SCC levels in normal subjects (n=64), patients with malignant disease (n=222), patients with benign disease (n=16) and pregnant women (n=13). At some sera, we compared SCC level with that of CEA. Serum SCC levels in normal subjects were 1.4±0.5 ng/ml (mean±S.D.). Cut off level was set at 2.2 ng/ml (mean±2S.D.). In some patients with squamous cell carcinoma of various sites, such as uterine, lung, esophagus, SCC levels were elevated. Serum SCC levels were positive in 49% (26/53) for cervical squamous cell cancer, 69% (18/26) for squamous cell lung cancer and 50% (17/34) for esophageal cancer. These positive ratios were higher than that at CEA. It was concluded that SCC determination would be useful in patients with squamous cell carcinoma.

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RADIOIMMUNOASSAY FOR α-HUMAN NATRIURETIC POLYPEPTIDE AND ITS CLINICAL APPLICATION
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In an attempt to elucidate a pathological significance of α-human natriuretic polypeptide (α-hANP), we established a RIA for α-hANP in human plasma. Extraction was done using Sep-pak C18 after acidifying plasma. The synthetic α-hANP was radiolabeled by the chloramine T method and purified by HPLC. RIA was performed by the delayed assay (4°C, 48h) and B/F separation was achieved by the 2nd antibody-PEG method. The antiserum (final dilution 1:106) recognized α-hANP and α-TANP equally and produced a linear standard curve between 5 to 1000pg/tube. Recovery of α-hANP from plasma ranged from 80-90%. The C.V. were about 10%. The concentrations of α-hANP in normal volunteers were 127±77 pg/ml (male, n=18) and 134±63 pg/ml (female, n=18), respectively. Furthermore, plasma levels were markedly elevated in patients with congestive heart failure and chronic renal failure, whereas that in patients with idiopathic edema was decreased. In conclusion, we have developed a RIA method for α-hANP and indicated an usefulness of the clinical application of this method.

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ASSESSMENT OF DIAGNOSTIC VALUE OF FIVE TUMOR MARKERS
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With the purpose of assessing clinical efficacy of various tumor markers plasma concentrations of CEA, TPA, CA10-9, A FP and Ferritin were measured by radioimmunoassay (RIA). The difference between the true positive ratio for carcinoma and the false positive ratio calculated in benign disease were used as efficacy index for the evaluation of clinical usefulness of markers. The tumor marker of which usefulness was appreciated solely by its combination with the order marker was a follow: CEA for colorectal carcinoma, A FP for hepatocellular carcinoma, CA10-9 for pancreas carcinoma, the combination of CEA and TPA for stomach and pulmonary carcinoma, and CA10-9 and TPA for bilialy tract carcinoma. The appropriate selection of a marker or a combination of markers should allow efficient detection of a target cancer.