

### Study on Radioimmunoassay of CEA Using CIS Kit

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Both the one step sandwich method and the Z-gel method have been developed for the conventional radioimmunoassay of CEA (Carcinoembryonic antigen) although they need a considerably large amount of plasma as test sample and include a complicated procedure of deproteinization.

This paper reports the clinical validation of CEA radioimmunoassay kit (CIS) and its comparison with the conventional one.

Method and Results; Radioimmunoassay was performed following the instruction for use of CIS kit. The reproducibility of standard curves, the value of  $B_0/T$  (%), precision, and the blank value were examined on this kit. The reproducibility of standard curves was excellent showing an average coefficient value of 6.9%, while the  $B_0/T$  (%) was found to be 19.8% on assay im-

mediately after the calibration and to be as low as 12.5% approximately 4 weeks after the calibration. From these data, the validity is considered to be shorter than 3 weeks.

The precision and sensitivity were estimated approximately 10% and 2.5 ng/ml respectively. Normal value (male 67 cases) was within N.D~4.7 ng/ml in an average of  $5.29 \pm 3.29$  ng/ml, and 92.2% of the normal values fell in the range of less than 10 ng/ml.

Thus, it was demonstrated with CIS's CEA-kit that it has the same sensitivity as the conventional method and needs no procedure of deproteinization, and that a test sample is as little as 50  $\mu$ l in volume.

In conclusion, this kit will be valued as a useful radioimmunoassay procedure at routine laboratory works.

### Evaluation of "Double Antibody Method" for CEA Determination

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Carcinoembryonic antigen (CEA) was determined by the "double antibody radioimmunoassay" in 235 sera and 39 urine specimens from 130 patients with various infections or malignant diseases and 14 normal control subjects. The normal values of CEA by the "double antibody RIA" were claimed from 0 to 10 ng/ml of serum. All urine and 139 serum samples were also assayed for CEA by the "one step sandwich method". The values by both methods were compared and correlated.

Reproducibility of the assay system was studied by using commercial control sera NMS-I and NMS-II which were produced by Nuclear Medical System, Inc. Values of CEA were from 7 to 16 ng/

ml in NMS-I and 5 to 8 ng/ml in NMS-II. Interassay coefficient variations were 22.2% and 17.5% respectively.

Serum CEA values were near 0 ng/ml in control subjects and slightly elevated in cases with infectious diseases without malignancy.

Serum CEA was markedly elevated in patients with cancer of the stomach, colon, rectum or lung. On the other hand, serum CEA was within normal ranges in patients with uroterial carcinoma.

The CEA values by "double antibody RIA" were eight times higher than those by the "one step sandwich method". Values by both methods, however, were well correlated ( $r=0.89$ ) except in

several samples. Urine CEA values showed good correlation ( $r=0.84$ ) between the two methods. However "double antibody RIA" showed thirteen times higher values than the other method.

The incidence of positive CEA tests agreed well in both methods for cases with cancer of the lower digestive tract and the lung. But sera of all cases with renal cell carcinoma showed normal CEA levels by the "double antibody method",

while serum CEA was positive by the "one step sandwich method" in 43% of renal cell carcinoma cases. Positive tests were obtained in 22% of bladder cancer cases by the former method and 75% by the latter method.

It was concluded from the present study that the "double antibody RIA" was highly specific for cancer of the digestive tract and the lung.

### **Plasma CEA Measured by RIA Using One Step Sandwich Method**

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Plasma CEA was measured by RIA Kit (Dainabot) based on one step Sandwich method.

The result was evaluated in comparison with our previously reported data of plasma CEA measured by Z-gel method.

Basic evaluation of the Kit included within assay error of 6-10% (C.V.), between assay error of 4% (C.V.) and recovery rate of 106-160%. Plasma CEA level was 18% lower than serum CEA level.

Plasma CEA level measured in 32 normal control was  $1.85 \pm 0.49$  ( $\bar{m} \pm 1$  S.D.), which was significantly lower than that measured by Z-gel method ( $2.11 \pm 1.15$ ).

Plasma CEA levels in 183 patients measured by the two methods correlated well with regression equation of  $Y(\text{Z-gel}) = 1.8X(\text{Sandwich}) + 2.0$  ( $r = 0.67$ ).

Twenty four of 26 patients with benign diseases who had false positive CEA level ( $>5$  ng/ml) by Z-gel method showed false positive CEA level ( $>2.5$ ) by sandwich method. Of 82 patients without carcinoma 62% was normal ( $<2.5$ ) in plasma

CEA level. Of 101 patients with carcinoma 38% was positive ( $>2.5$ ) and 13% showed CEA over 10ng/ml.

Ratio of positivity ( $>2.5$ ) was compared among primary organs of carcinoma. High positivity was observed in the colorectum (68%), lung (50%) and stomach (50%). Positive ratio was relatively low in cancer of esophagus (14%), and urogenital organs (29%). The higher CEA values were observed as the stage of carcinoma was advanced.

In cancer patients who received successful radical operation CEA level was relatively low before operation and was significantly decreased post-operation. In contrast, CEA level was high and become higher after operation in patients who recieved palliative operation.

Measurement of plasma CEA by sandwich method was useful for the detecion of advansed cancer and evaluation of treatment and course of cancer patients. The clinical value was just as same as that of CEA measured by Z-gel method. Though the former gives lower value than the latter.