Comparison of Three Methods of CEA Radioimmunoassay

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We have measured serum CEA levels in patients with various diseases by three methods of CEA radioimmunoassay; Double antibody technique, Zirconyl phospate gel saay (CEA-ROCHE Kit) and Sandwitch method (DAINABOT CEA RIA KIT).

Double antibody technique modified from the method of Egan et al. takes 3 days in whole assay but its procedure is very simple. The upper limit of the normal range in this technique is 10 ng/m*l*. Z-gel assay takes 2 days but requires troublesome procedures, those are extraction by perchloric acid and following dialysis. 5.0 ng/m*l* is the upper normal limit in this assay. Sandwitch method takes only about 24 hours and its procedure is simple and easy, and 2.5 ng/m*l* is the upper normal limit in this assay.

The correlation coefficient between double antibody technique (Y) and Z-gel assay (X) was +0.97 and the regression equation was $Y=0.97X-0.37$, and between Z-gel assay (X) and Sandwitch method was +0.59 and the regression equation was $Y=0.22X+0.54$.

In cases which were measured by all three methods, percent positivities of colon cancer were 58% by double antibody technique, 83% by Z-gel assay and 50% by Sandwitch method, and those of stomach cancer were 29%, 50% and 21% respectedly, and those of pancreas cancer were 57%, 71% and 43% respectedly. So percent positivities in maliganant diseases were lowest in Sandwitch method and highest in Z-gel assay. Especially percent positivity of stomach cancer by Sandwitch method was 21% which was very low compared with those by other two methods.

The diagnostic levels for malignant diseases were considered 40 ng/m*l* in double antibody assay, 10 ng/m*l* in Z-gel assay and 5 ng/m*l* in Sandwitch method.

It was considered that the difference in CEA levels among three methods was due to the purity of CEA molecules and reactivities of anti-CEA antiserum to non-specific cross-reacting antigens which were respectedly prepared in three methods.

Quality Control in Radioimmunoassay: Values and Reproducibility of Commercial Control Sera

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It is necessary to measure reference sera in each run of radioimmunoassay for obtaining reliable results. Long term supply, minimum differences of contents among bottles, stability and negative HB_sAG are all required for commercial sera. Constant values obtainable for any assay system used are also desired.

In routine radioimmunoassay measurements, commercial multi-contents control sera, NMS-I and NMS-II (Eiken Chemistry K.K.) were used for RIA control sera along with pooled serum. Reproducibility of control sera was compared with our own pooled serum.

Reproducibility of the values obtained in any assay studied was in general satisfactory as compared with pooled serum. Thyroxin was measured in thirty successive assays during this period. While pooled serum (M-I) showed the mean value of 9.99 ± 0.94 ug/dl, control serum (NMS-I) showed 12.91 ± 0.94 ug/dl on an avarage. The coefficient variation of the former determination was 9.41% and that of the latter was 6.97%. Both these results were considered to be satisfactory as between-assay variability of radioimmunoassay.