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 phosphate gel saay (CEA-ROCHE Kit) and Sandwich 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/ml. Z-gel assay takes 2 days but requires troublesome procedures, those are extraction by perchloric acid and following dialysis. 5.0 ng/ml is the upper normal limit in this assay. Sandwich method takes only about 24 hours and its procedure is simple and easy, and 2.5 ng/ml 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 Sandwich 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 Sandwich method, and those of stomach cancer were 29%, 50% and 21% respectively, and those of pancreas cancer were 57%, 71% and 43% respectively. So percent positivities in malignant diseases were lowest in Sandwich method and highest in Z-gel assay. Especially percent positivity of stomach cancer by Sandwich method was 21% which was very low compared with those by other two methods.

The diagnostic levels for malignant diseases were considered 40 ng/ml in double antibody assay, 10 ng/ml in Z-gel assay and 5 ng/ml in Sandwich 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 respectively 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 HBsAG 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 average. 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.
As for immunoreactive insulin assay, pooled serum of NMS-I and NMS-II were measured successively in each assay more than fifty times. Within-assay variavility of reference sera were all below 10%. Between-assay variabilities showed coefficient variation below 15%. There was no large difference in coefficient variation among pooled serum, NMS-I and NMS-II.

Other assays including T-3, T3RU, TSH, FSH, HPR, HGH, Gastrin, Cortisol, IgE, AFP and others showed satisfactory reproducibility within the range allowed as between-assay variability of radioimmunoassay. However there were significant differences between indicated values and values obtained by us, except HGH, FSH and Gigoxin of NMS-II. LH was not able to be measured because of very high value. Immunoreactive insulin was measured using three different kits. The values obtained were significantly different each other.

Therefor one of main reasons of difference between indicated values and values obtained was considered to be probably due to different assay system used. However, these control sera are maintained within permissible range as far as reproducibility is concerned, so that we could use them for the control of reproducibility of routine assay system. HBsAG was always negative by sensitive radioimmunoassay.

**Functions for Computation of Best Fitting Standard Curve in Radioimmunoassay of Hormones**

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In order to evaluate the functions for computerized standard curve calculation for RIA of hormones, interassay variations of standard hormone levels in 5 assays were determined using calculator YHP MODEL 30 (4kW) and HITAC-20 (32 kW).

The standard curves were linearized by YHP MODEL 30 using raw, logit, arcsine or probit for B/B0 on vertical axis and logarithm of hormone concentration on horizontal axis. The interassay variations were also calculated by HITAC using Rodbard's best fitting function (RBFF) program. The hormones examined included TSH, LH, FSH and IRI by double antibody, T3 by dextran coated charcoal method and cortisol by polyethleneglycol method. RBFF turned out to show significantly smaller variation than those of other 4 functions especially in the range of high or low concentration of hormones. Among the 4 functions for linearization, logit gave the least error for TSH, FSH, T3 and C-AMP while probit for cortisol, LH and IRI. The manual drawing of the standard curve by inspection resulted in the range of .30 to .90 of B/B0. It is concluded that linearization of standard curve by logit or probit transformation is practically useful in automatic calculation of hormone levels especially in the range of .30 to .90 of B/B0. RBFF covers, however, much wider range of hormone concentrations with smaller interassay variations establishing the validity of large computer system.

**Determination of TSH by Simultaneous Equations**

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The currently available Competitive Radioassay has been shown to have some defects. Thus we have tried to reform this current method of Competitive Radioassay, applying it to the detemi-