STATE OF THE ART OF THE RADIOIMMUNOASSAY IN JAPAN:
RESULT OF QUALITY CONTROL SURVEY SINCE 1978 TO 1982.
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We performed 4 quality control surveys since 1978 to 1983, by sending external quality control samples of analytes to participating institutes. The results of RIA of insulin, TSH and T4 were analyzed by analysis of variance. Both of between-kit variation and within-kit variation for insulin and TSH were remarkably large in 1978 and 1979. Both of them considerably decreased and reached to nadir in 1981 and 1982. Between-kit and within-kit variation of T4 were rather small and remained at the same small level throughout these periods. This result indicates that the quality of RIA of insulin and TSH improved considerably in the year of 1981 to 1982 and that of T4 which is better than those of insulin and TSH from the beginning stays the same level.

In 1981, we have performed a quality control survey of radioimmunoassay of eight analytes, participated in by 249 laboratories of various types throughout Japan. For the purpose of the external control survey, lyophilized specimens containing two different concentrations of each analyte were sent to the participating laboratories, which supplied both their assay values and their raw data for the standard curves and for the samples. The individual data for the standard curve were analyzed by the RIA data-processing program described by Faden and Rodbard. The precision profile obtained for the individual assay was used as the estimate of the quality of each assay. Although there was a wide scatter in assay values, the quality of the assay by the individual laboratories was not the major contributor to this scattering, because the values they reported for the assays and precision profiles of the standard curves were almost identical with those obtained from the kit manufacturers. When the reported assay values were analyzed according to the brand of kits, by analysis of variance, the treatment mean square due to difference in the make of the kits significantly exceeded the error mean square due to within-kit variation in the assay of insulin, T4, TSH, cortisol, gastrin and digoxin. The CVs for between-kit, within-kit, between-assay and within-assay variations (the latter two aspects were studied in a representative laboratory, for convenience of comparison) were about 20, 15, 13 and 7%, respectively. Because the observed within-kit variation is of almost the same magnitude as that expected from the combination of within-assay and between-assay variation, the skill of the users probably was equal and the accuracy and precision of the kits probably had the greatest impact on assay variation. This survey also emphasizes the criteria for commercially available RIA kits.

To further reduce the between-kit variation of insulin RIA, the common standards prepared by us were sent to representative institutes. They were asked to provide the result of the assay of quality control sample by kits employing both kit standards and common standards. The result measured by common standards showed significantly reduced between-kit variation, indicating the difference in the potency of standards was the major cause of large between-kit variation.