Special Announcement

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SUMMARY REPORT OF 5 YEARS' EXPERIENCE IN IN VITRO TEST COMMITTEE, JAPAN RADIOISOTOPE ASSOCIATION.

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Since 1978, In Vitro Test Committee of Japan Radioisotope Association has performed the nation-wide control survey every year. The main purpose of this survey is that to know the present status of the precision of the determinations performed by radioimmunoassay or its related in vitro assay, and to attempt for the improvement of the assay.
At the first trial, samples of high and low content (A and B) of thyroxine, insulin, alpha-fetoprotein, triiodothyronine and thyroid stimulating hormone were sent to the users, and results obtained were analysed. The values obtained by CPBA showed larger variation than RIA. The determination of small molecular substance showed less scattering than large molecular substance, some of which showed large variation. In the second survey, 7 items were selected, and from this survey, the names of kit makers and importing companies were opened for publication with the agreement of the Association of Radiopharmaceuticals. The users were graded as A to F according to their results reported. The problems of CEA assay, which show the big variation of between assay were stressed. Since third survey, computerized data processing program developed by Dr. Rodbard of NIH, USA was employed for the analysis. Samples were selected according to the characteristics of the standard curves of various kits. For the assay of insulin, an attempt was made to use common standard substances, and the values obtained were compared to those obtained by using the kit standards. The values of determination by 6 kits became closer and C.V. improved. The results of the 3rd survey were presented at the 3rd World Congress of Nuclear Medicine and Biology, and published in Clinical Chemistry.
At the 4th survey, 10 items were surveyed and analysed by similar method, and comparison was also made with EIA.
At the 5th survey, items were increased to 21, and analysis was done extensively.

From these experiences, it can be stated that the technical aspects are generally satisfactory except some laboratories. The between kit variations, batch to batch variations, precision profiles, the problems of antigen, antibody and standard substances etc. of the assay reagents should be improved in future. It is hoped to continue this kind of assay survey for the benefit both users and reagent manufacturers.