

## 82

## QUALITY CONTROL OF RIA KIT.

(TO: KIT SUPPLIERS)

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We talk about unstable quality of RIA Kit under poor management system, which was observed during 1982 - May 1985 and maker's response to it. Claims in regard to the quality of RIA Kit were as follows.

- S.57: \* BIAS - By change of Antibody-lot of Insulin  
\* Label misprinted - On Max. norm concentration value at HPL
- S.58: \* BIAS at CEA  
\* BIAS at ESTRIOIOL - Caused by Enzyme in crude material step  
\* Low Tendency on data - By change of TBG norm concentration
- S.59: \* BIAS at AFP  
\* Low Tendency on Data - By change of CEA norm concentration  
\* Ununiformity of Solid phase antibody value at T<sub>4</sub>  
\* Ununiformity of RAST Allergendisc
- S.60: \* Lifting on score judgment of RAST Allergendisc(House-dust 1)

## 83

## STUDY ON STABILITY OF VERY SMALL SUBSTANCES IN SERUM-STABILITY OF FRESH SERUM UNDER THE DIFFERENT PRESEVATION CONDITIONS.

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Studied the influence of serum used for RIA on measured value covering 18 items under the different preservation conditions by 1)freezing 2)repeat of freezing and thawing 3)4°C and 4)room temperature. Stability of each substance was judged by the value measured more than once a week and remained within the range of mean  $\pm 2SD$  value under the 1st condition. Results:1)TSH,AFP,BMG,IRI,CPR, VB12,FA,etc.:became unstable at room temperature within a week. 2)CEA,BMG, ELASTASE 1,IRI,CPR,etc.:became unstable at 4°C within one month. 3)CEA,Ferritin, IRI,CPR,FA,etc.:became unstable less than 20 times of repeat of freezing and thawing. The variation was different:With time lapse,measured values of IgE,IRI, FA,etc.showed lower whilst those of T3U, CEA,Ferritin,etc.did higher. In case of T3 RIA and TBG showed high values first, then became lower. Measured values under the conditions 2),3) and 4) varied largely even within the above range. Even perishable serum is measurable on some items. These facts imply that RIA catches immunological radical as a quantity of substance.

## 84

## THE DEVELOPMENT OF AN EFFICIENT DEVICE FOR RADIOIMMUNOASSAY REPORTING USING THE MINI-COMPUTER.

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In spite of its urgent demand and easy feasibility, there are little number of efficient devices reported for the reporting system of radioimmunoassays which are increasing in number and variety. Moreover, in vitro assays should be done by limited number of persons due to the shortage of national finance at this time. Thus, we tried to make a new design to save time and hand writing trouble, using a mini-computer system.

In our hospital, the most common 6 items, comprising 40% of total samples, are assayed in our own laboratory, and the remaining 50 items (60%) are sent to the contracted private laboratory for assay procedure. Only two persons are available for radioimmunoassay in our institution.

The results from home assays are transferred to the mini-computer directly from the gamma counter and those from the private laboratory are carried through the on-line system (NTT) to the same computer. This system omits the unnecessary work and miswriting, easily facilitates the data retrieve and transfer, and makes it possible to report the results from two different laboratories on the one format, which was previously done by hand writing on the separate sheets.

## 85

## FUNDAMENTAL STUDY AND CLINICAL EVALUATION ON RADIOIMMUNOASSAY OF SCC ANTIGEN USING SCC RIA KIT (DAINABOT)

- WITH SPECIAL REFERENCE TO LUNG CANCER - I.Nishiguchi, K.Nakamura, S.Tominaga, Y.Takagi, A.Kubo, F.Kinoshita, S.Hashimoto, Keio University School of Medicine, Tokyo.

Radioimmunoassay of SCC antigen in the sera is useful for early diagnosis or staging of uterine cervical cancer. We measured SCC antigen in the sera of patients with various lung diseases using SCC RIA Kit (Dainabot). There were few effects of dilution, hemolysis and storage of sera on the assay, and we found good recoveries for any measurements. Serum SCC antigens were assayed in 178 cases consisting of 65 normal subjects and 113 with lung diseases. Here we set cut-off value of 2.2ng/ml. For squamous cell ca. of the lung, a positive rate of SCC was 70% while that of adenoca. was 22%. As a function of the stage, the positive rates were 50% of stage I, 63% of stage II, 78% of stage III and 70% of stage IV. We have observed some cases that tumor recurrence could be predicted preceding the chest x-rays and also that therapeutic effects could be evaluated from the decrease of serum SCC antigen. Serum SCC antigen could be used as a tumor marker of lung squamous cell ca.