

### Evaluation of RIA Kits and Commercial Control Sera

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Measurements of serum hormone concentrations in the patients with endocrine disorders are very important for diagnosing the disease correctly. At present many kinds of kits for measuring the concentrations of serum hormones and of control sera for standardizing the assays are available from commercial sources. This studies were performed to evaluate the variances among assay kits or control sera by measuring thyroxine ( $T_4$ ), triiodothyronine ( $T_3$ ), TSH, insulin (Ins), and growth hormone (GH) in 13 different kinds of control sera from five commercial sources with 32 kits available from 9 commercial companies (12 for  $T_4$ , 6 for  $T_3$ , 6 for TSH, 7 for Ins and 3 for GH respectively).

In general, values for a control serum varied greatly according to the kits employed and variations of values among the kits varied greatly according to control sera employed. Actual values obtained by some kits were not always consistent with those shown in the instructions attached to the sera. In measurements by CPBA,  $T_4$  concen-

trations of any control serum showed big variances between kits. The values by RIA kits, however, were a little less variant than CPBA, and values by CPBA were quite different from those by RIA in some kits ( $17 \mu\text{g/dl}$  and  $0.5 \mu\text{g/dl}$ ). Of  $T_3$  measurement, most of the actual values were consistent with the expected and variances between kits were not so large only when the expected values were around normal range. TSH concentrations by two of six different kinds of kits showed abnormally high values in the control sera, the TSH concentrations of which were supposed to be less than  $10 \mu\text{U/ml}$ . Ins and GH concentrations seemed relatively consistent with values between sera when certain kit was used exclusively, and variances between kits were less than those in thyroid hormones.

These results have shown that the variances among RIA kits and among commercial control sera are so great that it is definitely necessary to make some efforts to improve the measurements with RIA kits.

### Fundimental Studies on Serum Total $T_3$ and Estriol Radioimmunoassay Kit (Seralute Total T-3 RIA and Estriol RIA)

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Measurement of serum triiodothyronine ( $T_3$ ) as well as thyroxine is necessary for managing of patients with various thyroid disease. We have studied advantage, disadvantage of one of these  $T_3$  radioimmunoassay procedures, Seralute total T-3 RIA kit (Ames Company).

When this kit is used, the centrifugal procedure is not necessary because a Sephadex column was used to separate "bound" and "free".

(1) In the ordinary procedure, seven drops of  $^{125}\text{I}$ -Liothyronine was dropped onto the column. To shorten the process time, the procedure was modified—that is,  $0.5 \text{ ml}$  of the Reagent was added

by an automated pipetting equipment.

(2) Comparison between Seralute  $T_3$  RIA kit (column method) and Dinabot  $T_3$  RIA kit (charcoal deatran method) was made.

(3) Also, basic and clinical evaluation of Seralute estriol kit was made.

The use of  $0.5 \text{ ml}$  of  $^{125}\text{I}$ -Liothyronine Reagent instead of adding seven drops enhanced accuracy and precision of the RIA assay. Reproducibility of the assay was 7.5% (C.V.). Correlation between  $T_3$  values measured by the column method and the charcoal dextran method was good ( $r=0.88$ ). Also, reproducibility of Ames estriol kit was

good (C.V.=13.7%). In the 10-months pregnant women, serum estriol concentration was  $13.9 \pm 8.9$  (SD) ng/ml. From the result, we concluded

that radioimmunoassay of serum T<sub>3</sub> and estriol using the RIA kits (Ames Company) would be sufficiently usable and promising ones.

### **Experimental Study on Detoxication of Hepatitis B Surface Antigen (HBs-Ag) in Reference to Radioactive Waste Disposal**

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Small medical apparatuses directly contacted with human blood possessing hepatitis B surface antigen (HBs-Ag) have potential sources involving viral hepatitis to a person handling them.

The authorized agency responsible for radioisotope waste disposal in Japan usually refuses handling and collections of any materials directly referred to human blood, if special antiviral procedures have not previously taken against HBs-Ag, because they are afraid of infection of viral hepatitis.

The objective of the study is to investigate effective and practical methods of chemical detoxication of HBs-Ag which is involved in small apparatuses used in nuclear medicine. 0.5 to 5 ml plastic syringes were used as small apparatuses in the study. The inner surfaces and needles were contaminated with HBs-Ag by means of putting 0.5

to 1 ml of HBs-Ag positive human blood into the syringe. Then, the inner surfaces and needles were rinsed away with 1 ml solution of saline or of following disinfectants of various concentration; NaClO, PACOMA\*, IRGASAN-DP300\* HIBITANE\*, alcoholic glutar-aldehyde or CLEAN 99L\* (\*abbreviates trade marks), The detoxication of HBs-Ag was examined by radio-immunoassay with AUSRIA-II kits on 0.2 ml of rinsing solution above mentioned.

The results of assay showed that 10000 PPM NaClO and 2.5% alcoholic glutar-aldehyde were the most effective, completing detoxication in short time; 0.5% IRGASAN-DP300 and 5000PPM NaClO did effective in a certain condition alone or less effective; and PACOMA, HIBITANE and CLEAN 99L did not effective.

### **Measurement of Serum Digoxin Using Digoxin <sup>125</sup>I Radioimmunoassay and Its Clinical Application**

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Digoxin is the most widely prescribed cardiac glycoside in order to control of congestive heart failure and certain abnormalities in the cardiac rhythm. Measurement of serum levels of digoxin is important in the clinical management of patients receiving this drug.

Recently, the Digoxin <sup>125</sup>I-Imusay kit<sup>R</sup> was provided by Abbott Laboratories. Fundamental problems on performing this assay systems was investigated and its clinical usefulness was evaluated.

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Standard curve was shown quite linear with rapid decline on linear scale during 0.0 to 2.0 ng/ml of digoxin concentration. Per cent bound was increased from 0 to 60 minutes at incubation and it reached plateau after 60 minutes. The temperatures during the assay were tested at 4°, 17°, 25°, and 37°C, respectively. Then the most precise condition for the assay was obtained at 25°C. Coefficient of variation in within-assay was 9.5% and the