E: In vitro, RIA

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STUDY ON STABILITY OF VERY SMALL QUANTITY SUBSTANCES IN SERUM --- STABILITY OF FRESH SERUM AT ROOM TEMPERATURE ---. M. Usami

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Having reported stability of pool serum at room temperature in comparison with that of pool serum to this meeting, we present stability of fresh serum at room temperature in comparison with that of pool serum to this meeting.

Methods:

Preservation of fresh serum was performed under the same conditions as those for pool serum: (1) dispersed and freezing (2) repeat of freezing and thawing (3) at room temperature. Each substance was judged stable when its measured value remained within the range of mean ± 2SD value under the first condition.

Results:

(1) Stable for about 1 week: BMG, IRI, CRP
(2) Stable for about 2 weeks: AFP
(3) Stable for about 1 month: T3U

Substances in fresh serum were found stable for shorter period than those in pool serum. Especially, T3U's stability showed drastic change: 115 days in pool serum; about one month in fresh serum. This difference may be brought about from pool serum's repeated procedure of freezing and thawing. As for other items, we will have finished the examination by this meeting.

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THE MINIMAL DETECTABLE CONCENTRATION (MDC) OR SENSITIVITY OF RADIOMUNOASSAY

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Review of 4 Japanese literature on the methods of RIA revealed only 36.4% of the papers describing about MDC. About 40% of those described only value of MDC without any statistical consideration. Most prevailing methods are dilution method, 2sd method and 95 % method. Therefore some statistical consideration about these methods were reported in the present paper. In the dilution method a special assay has to be run for measuring MDC. But no problem exists to obtain statistical significance. In other methods MDC can be obtained from data of routine assays. But 2 assumptions are necessary. One is the assumption about normal distribution of zero assay. The other is the assumption about the same standard deviation of zero and minimal detectable conc.

In order to obtain MDC with 95 % significance level more than 5 of zero assay must be performed. In 95 % method, number of zero assay is varied depending on the sd of zero assay. Then sd of each assay was used, significance level changed from 95 % to 80 %.

But with use of pooled sd, more reliable MDC can be obtained. In a case of alpha fetoprotein MDC with 95 % significance level was 2.2 with 2sd method, 3.2 with 95 % method using each sd and 9.9 with method using pooled sd. Stress was placed on describing "method and significance level" so that one can compare data from different papers.

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TRIIODOTHYRONINE (T3) UPTAKE ASSAY WITH MAGNETIC FORCING AS THE METHOD FOR BOUND-FREE SEPARATION.

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Clinical utility of the assay of Magic Tuptake (Corning, Medical and Scientific) was evaluated. This method employs bovine serum albumin, covalently coupled to para-magnetic particle as the secondary T3 binder. In the test procedure, the serum specimen was incubated with the T3 binder and labelled T3, and bound and free fraction were magnetically separated. The precisions of the assay (intra- and interassay coefficient of variation) ranged from 0.94 to 2.61% on high, low, and midrange Tuptake serum pools. Correlation coefficients of the Magic Tuptake value with Triosorb-S and Spac-Tuptake values were excellent (r=0.918, p<0.001), and r=0.921, p<0.001 respectively). The Magic Tuptake value in the normal subjects was 31±2.5% (n=85) (mean±S.D.), and this was elevated in hyperthyroidism (46±0.5%, n=24, p<0.001), and in patients with decreased thyroxine-binding globulin (TBO) (47±2.9, n=3, p<0.001), and lowered in hypothyroidism (21±7.2, %, n=15, p<0.001) and in pregnancy (18±3.1, %, n=7, p<0.001). A high correlation between the Magic Tuptake value and unsaturated TBO concentration (r=0.748, n=78, p<0.001). These results indicate that the Magic Tuptake method is reliable, reproducible, easy to handle, and capable of use in large-scale indirect measurements of serum concentration of TBO not binding thyroxine (unsaturated TBO).

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CLINICAL EVALUATION OF AMALEX FREE T, RIA KIT.


The purpose of this study is to make clinical evaluation of Amalex Free T, RIA kit. Subjects were 40 normal controls, 13 untreated patients with Graves' disease, 12 treated patients with Graves' disease, 27 patients with hypothyroidism, 18 patients with thyroid carcinoma, 5 patients with liver cirrhosis and 8 patients with chronic rheumatoid arthritis. Serum free T was measured by a dialysis method and Amalex Free T, RIA kit. The values for free T, by this kit and by dialysis was as following: normals 4.0±10.56, 2.8±0.67 pg/mL (mean±SD, n=30) untreated Graves' patients 17.6±4.82, 8.0±2.57 (n=13), treated Graves' patients 3.1±1.37, 3.5±1.17, 5.7±1.57 (n=12), patients with thyroid carcinoma (n=18), patients with liver cirrhosis 2.00±0.39, 3.2±0.33 (n=5), patients with chronic rheumatoid arthritis 2.48±0.41, 2.14±0.61 (n=8), respectively. Amalex Free T, RIA kit is clinically useful, although several subjects were observed whose values for free T were different between by this kit and by dialysis.