44

COMPUTERIZED STATISTICAL QUALITY CONTROL FOR RADIOASSAYS. K.Imamura,T.Takahashi,F.Asaba, A.Sato,Y.Sasaki,K.Hoshi,K.Someya and M.Fujii . St.Marianna University School of Medicine ,Kawasaki.

Since radioassays have become widely used as routine clinical examinations, importance of quality control (Q.C.) has been acknowledged in order to provide reliable data. In our laboratory Q.C. has been performed for the past two years. With the purpose of reducing technologists'work load and saving time, data handling for Q.C. has been automated using a computer. Three types of Q.C. procedure were included:for the evaluation of assay precision, 1)analysis of standard curves 2)construction of responce error relationship(RER), and for the evaluation of assay bias 3)analysis of control sera of two different ranges. Using registered data the Q.C. program works automatically following data processing. The final print out is the judgement for accepting or rejecting of an assay.

Using the proposed rejection criteria none of 200 assays was rejected because of bad precision, and 9 of 200 assays had to be rejected for increased bias. Therefore,vias was the major problem in the Q.C. of radioassay in our laboratory for which control sera is the sensitive means of Q.C. The establishment of the most appropriate criteria for rejection in each laboratory and for each assay system remained to be studied.

45

FUNDAMENTAL STUDY OF FULL AUTOMATIC RADIOIMMUNOASSAY SYSTEM CONCEPT-4 ; DETERMINATION OF SERUM CORTISOL. Y. Ito, A. Iyoku and K. Akaishi. Special Reference Laboratory. Tokyo.

Determination of serum cortisol by CONCEPT-4 was performed and the following results were obtained.

The standard curve of this assay system revealed the sensitivity of 1.0 $\mu g/dl$ at the B/B_0 of 90%.

The withinassay variation ranged from 3.5 to 8.6% (c. v.) and betweenassay variation from 7.9 to 9.4% (c. v.).

The data using this system were well correlated with those of other kits ;

Cortisol Daiichi ($r=0.92$, $n=50$),

Cortisol Eiken ($r=0.97$, $n=50$),

GammaCoat [^{125}I] CORTISOL ($r=0.95$, $n=50$).

Serum cortisol level of 123 normal subjects at 9:00 a.m. ranged from 4.7 to 19.4 $\mu g/dl$.

46

APPLICATION OF COMPUTER PROGRAMS FOR QUALITY CONTROL OF RIA. A.Harada,K.Tabushi,Y.Watanabe,S.Ito,T.Nakajima,B.Kado,M.Sakura,Y.Sasaki and T.Nagai. Saitama Cancer Center,St.Marianna University School of Medicine and Gunma University School of Medicine. Ina, Kawasaki and Maebashi.

Quality control(Q.C.) of RIA based on WHO recommendation was automated using a minicomputer installed in our nuclear medicine laboratory (Scintipac 230). The computer program includes construction of responce error relationship (RER), precision profile and Q.C. chart using3 types of Q.C. samples. Our criteria for rejection were as follows: a)for the rejection of a sample;(1)S.D. of duplicate measurement is above the RER with slope of 0.1. b)for the rejection of a whole assay;(1)slope of RER is greater than 0.04. (2)2 of 3 Q.C. samples were out of 95% confidence limits on Q.C. sharts. In our experiance during past 10 months, a total of 18 samples (T3 1, T4 3, TSH 6, PRL 7, IRI 1) and one whole assay(IRI) were rejected. Precision profile provided a useful index for the evaluation of assay technique and change of the quality of RIA kits.

47

ESTIMATION OF THE URINARY ALDOSTERONE. T. Suzuki,Y.Kanno,S.Ichinohe,K.Nakagawa and T. Ito. Self Defense Forces Central Hospital, Tokyo.

The urinary ALD was measured by ALDOSTERONE RIA KIT and the following results were obtained.

1) Ten percent solution of BSA instead of Free Serum ALD can be used as the diluent of the urine in ALDOSTERONE RIA KIT.

2) The upper limits of Free-ALD, HCl-ALD and β-Gl-ALD in the urine diluted with 10% BSA were 1.6, 9.0 and 9.5 μg/dl respectively.

3) The values of urinary conjugated HCl-ALD and β-Gl-ALD were approximately 3.5 times and 4 times as much as that of Free-ALD respectively.

4) A good correlation was obtained among the results of three methods (HCl-ALD, β-Gl-ALD and Free-ALD).

5) No difference was found in the values of the urinary ALD in the healthy subjects and the patients with essential hypertension, kidney diseases and acute liver diseases.