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FUNDAMENTAL AND CLINICAL STUDIES ON A HIGH SENSITIVE IRMA FOR TSH (ELSA TSH KIT). F. Handa, S. Jeong, Y. Habuchi, S. Bito, Y. Saiki, H. Yamaguchi, H. Ito, M. Hino, K. Ikekubo, T. Ishihara and N. Waseda. Kobe General Hospital, Kobe.

Fundamental and clinical studies on a high sensitive IRMA TSH kit were performed and compared with a sensitive double antibody TSH RIA (DA-RIA). The smallest amount of TSH detectable was 0.1 μ U/ml. Recovery and dilution tests gave satisfactory results. Intra-assay and inter-assay C.V. were 4.45-6.40% and 7.26-15.18% respectively. Serum TSH was detectable in all of 48 normal subjects. The mean concentration was 1.13 ± 0.89 (SD) μ U/ml with a range from 0.27 to 5.40 μ U/ml. Serum TSH levels were undetectable in all of 20 untreated Graves' disease and all 4 subacute thyroiditis patients. All 11 primary hypothyroid patients had high TSH levels ($>68 \mu$ U/ml). TRH tests were performed in 9 patients with thyroid disease and 3 patients with pituitary tumors. Serum TSH were measured using both radioassays. All 6 patients with Graves' disease had no TSH responses to TRH by both radioassays. TRH test results obtained by both assays showed similar TSH response patterns in 3 patients with Hashimoto's disease and 3 patients with pituitary tumor. Serum TSH levels by ELSA kit correlated quite well with those by DA-RIA ($n=122, r=0.95, Y=1.02X-0.4$).

In conclusion, this high sensitive IRMA kit is simple to do and clinically very useful for the diagnosis and treatment of the patients with Graves' and other thyroid disorders.

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BASIC AND CLINICAL EVALUATION OF THE MEASUREMENT IN THE SENSITIVE TSH-IRMA. E. Otsuka. Yamato City Hospital, Yamato.

The synthesis and the secretion of the thyroidal hormone are controlled with TSH which is secreted from the pituitary. It is well known, the negative feedback mechanism exists in the pituitary and thyroid.

RIA method for TSH was utilized clinically, but can't distinguish normal from low value.

Recently, the sensitive TSH-IRMA method using monoclonal antibody has been developed to resolve this problem.

So, we report fundamental and clinical evaluation of TSH kit "DAIICHI" II.

As the basic studies, the standard curve, the intra- and interassay variation, the dilution test and the recovery test, the incubation time and temperature were performed. Also, this method was compared with TSH-RIA as usual.

As the clinical studies, TSH values in 80 normal subjects were measured. These mean value S.D. is $1.4 \pm 0.87 \mu$ U/ml (0.3-3.9). TSH values in 50 cases with thyroidal diseases (untreated hyperthyroidism, treated hyperthyroidism and hypothyroidism) were measured. These 3 groups were divided clearly. Also, in few cases with hyperthyroidism or subacute thyroiditis were measured TSH and thyroidal hormones value with their clinical course.

In conclusion, the clinical value of the sensitive TSH is reported.

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CLINICAL EVALUATION OF HIGH SENSITIVE IMMUNORADIOMETRIC ASSAY FOR HUMAN THYROTROPIN. Y. Tokuda, K. Kasagi, K. Tomita, T. Kousaka, K. Arai, Y. Iida, K. Endo, J. Konishi, and K. Torizuka. Kyoto University School of Medicine, Kyoto.

We evaluated the high sensitive immunoradiometric assay (IRMA) kit for TSH "RIA-gnost hTSH" and reported its clinical application. The sensitivity of the assay was 0.04 μ U/ml and no crossreactivity with hCG, LH or FSH was observed. Taking mean \pm 2SD of 27 normal subjects as normal, it ranged from 0.31-3.89 μ U/ml. In all 44 untreated patients with Graves' disease, the TSH concentration was less than 0.06 μ U/ml. It was less than 0.2 μ U/ml in all 3 and 6 thyrotoxic patients with subacute and painless thyroiditis, respectively. In 10 out of 20 patients with euthyroid Graves' disease, it was below the normal range. In 7 out of 11 relapsed cases of Graves' disease, serum TSH concentration revealed to be lower than the normal range 1 to 12 months before the manifestation of clinical symptoms and elevation of serum thyroxine and triiodothyronine.

Measurement of serum TSH concentration by high sensitive IRMA method was useful for diagnosis of various thyroid disorders and for the follow-up of the patients with Graves' disease.

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CLINICAL EVALUATION OF HIGH SENSITIVE TSH IRMA FOR EVALUATING THE FUNCTION OF THE SECRETING TSH ON PITUITARY. R. Kawata, A. Nishikawa, M. Murakami, Y. Taruoka, S. Satoh, Y. Takamatsu, M. Suehiro and M. Fukuchi. Department of Nuclear Medicine and RI center, Hyogo College of medicine, Nishinomiya, Hyogo.

The high sensitive TSH IRMA using monoclonal antibody was studied for clinical evaluation of various thyroid status, especially secondary hypothyroidism with TRH-test. The high sensitive TSH IRMA used was a TSH RIABEAD II. The minimal detectable dose obtained was 0.01 μ U/ml. Serum levels of TSH were determined in 46 normal subjects, and 103 patients with thyroid disease. In normal subjects, it ranges from 0.28 to 4.7 μ U/ml, 24 among 26 patients with untreated Graves' disease was less than 0.01 μ U/ml. In 12 patients with euthyroid Graves' disease, the mean TSH level was $1.6 \pm 1.2 \mu$ U/ml, in 17 patients with primary hypothyroidism was $66.3-66.4 \mu$ U/ml. In 5 among 8 patients with secondary hypothyroidism, however serum TSH level was detected. In these patients, the response of TSH to TRH was also observed. While in 2 among 3 patients that was not detected basal serum TSH level, the low response of TRH-test was observed and in another patient, there is no response.

These data suggested that the high sensitive TSH IRMA was useful for clinical evaluation for pituitary TSH reserve.