INTRA AND INTERLABORATORY EVALUATION OF COMMERCIAL RECOMBINANT THYROTROPIN FOR THE PREPARATION OF RADIOASSAY REAGENTS.

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Recombinant human thyrotropin (rec-hTSH) obtained from transformed CHO cells has been used, in comparison with high quality pituitary thyrotropin (pit-hTSH), for radioiodination and for the preparation of a secondary standard to be used in both radioimmunoassay (RIA) and immunoradiometric assay (IRMA).

I-125-rec-hTSH was found to be identical to I-125-pit-hTSH in its binding and chromatographic characteristics including molecular properties like Stokes radius, in its labelling and storage stability and in the fact that it did not introduce any significant bias in the determination of unknown serum samples. A preparation of rec-hTSH was calibrated against a local secondary standard as well as against two well known international reference preparations (NIDDK-hTSH-RP-1 and WHO-IRP-80/558) in IRMA and RIA assay designs. While in the RIA system NIDDK-anti hTSH-3 polyclonal antibody was used, in the IRMA two commercial preparations were used: a monoclonal as detecting antibody and a polyclonal as capture antibody. In both types of assay the recombinant standard preparation presented significant parallelism when compared to pit-hTSH and allowed an unbiased determination of unknown serum samples. The specific activity of rec-hTSH, calibrated against the WHO-IRP, was 7.7 IU/mg of protein, determined by IRMA and 7.1 IU/mg, when determined by RIA. A rec-hTSH secondary standard (BRP-3) was thus prepared and calibrated against WHO-IRP-80/558, a large number of ampoules being distributed to 17 countries, already receiving our pit-hTSH standard (BRP-2) in Latin America, Asia and Africa, in order to validate the new preparation through an international collaborative study.