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APPLICATION OF A COMPLETE SET OF hTSH IMMUNORADIOMETRIC ASSAY (IRMA) REAGENTS PRODUCED AT IPEN-CNEN/SP TO NEONATAL HYPOTHYROIDISM SCREENING PROGRAMS IN LATIN AMERICA.

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Clinical determination of human thyrotropin (hTSH) has been considered the most sensitive and specific index of thyroid status, being also utilized in the neonatal screening for hypothyroidism. A complete set of in bulk reagents for neonatal IRMA was prepared in our laboratory, consisting of recombinant hTSH standard in filter paper, radioiodinated anti-hTSH monoclonal antibody and magnetic anti-hTSH solid phase. The quality of these reagents was compared with that of a well-known commercial kit (DPC, Los Angeles, USA) and both systems were applied to the Costa Rica screening program. Functional sensitivities of the order of 2mIU/L were obtained for the two systems, together with comparable precision profiles (n=500). Commercial quality control samples values (DPC, Baxter and CDC-Atlanta) showed good accuracy and the determination of unknown samples provided a highly significant correlation ($P < 0.001$) between the two methods. In conclusion, we can provide highly economical in bulk reagents with adequate sensitivity, accuracy and precision to be used in neonatal screening programmes, especially interesting for Latin America and developing countries in general.

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