

TRACEABILITY OF IMMUNORADIOMETRIC PROTEINE HORMONE MEASUREMENT TO REFERENCE STANDARDS

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AIM: Comparability of laboratory diagnostic test results is the goal in laboratory medicine. Traceability to appropriate measurement standards is a part of the strategy that could enable to achieve it. As a component of quality control at INEP, traceability of measurement by IRMA hCG (INEP) and IRMA TSH (INEP) to current reference preparation for hCG and hTSH is assessed.

MATERIAL AND METHODS: Reference preparation: The fourth international standard (IS) for chorionic gonadotrophin (NIBSC code 75/589) and the second international reference preparation of thyroide stimulating hormone, human, for immunoassay (2nd IRP hTSH, NIBSC code 80/558) were obtained from National Institute for Biological Standards and Control (NIBSC), a World Health Organization International Laboratory for Biological Standards. Recovery, as recommended method for the measurement of reference preparations in immunoassays, was performed by adding known concentrations of IS hCG and IRP hTSH to known (previously measured) concentrations of human sera. All measurements were done in accordance to manufacturer instructions, in triplicate. Linearity of two assays was also assessed.

RESULTS: The results obtained for a recovery by IRMA hCG (INEP) in the range from 90 % - 119 % demonstrated traceability of the hormone measurement. INEP's kit was previously calibrated against 3rd IS (code 75/537) and the finding of our testing is in agreement with collaborative study that the new IS 75/589 did not differ significantly from the previous standard in biological or immunological assays studied. The results obtained for a recovery by IRMA hTSH (INEP) in the range from 83 % - 115 % also demonstrated the expected traceability of the hormone measurement as the assay was calibrated against current 2nd IRP TSH.

CONCLUSION: The results obtained for recovery by IRMA hCG (INEP) and IRMA TSH (INEP), together with assays' specificity and analytical precision showed that the present assays could be used for accurate quantitative measurements of hCG and TSH in human serum.