

QUANTITATIVE DETERMINATION OF FREE PROSTATE-SPECIFIC ANTIGEN BY IMMUNORADIOMETRIC ASSAY DEVELOPED BY INEP

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AIM: Prostate-specific antigen, PSA, extracellular serine protease, is expressed by the epithelial cells of the acini and the ducts of the prostate. Serum PSA is found in complexes with few serine protease inhibitors as well as in its free form. Quantitative determination of total prostate specific antigen, tPSA, is widely used for early detection and monitoring of prostate cancer. However, there is a «gray zone» of elevated concentrations of tPSA associated with both malignant and benign or inflammatory prostate conditions. In order to increase specificity and sensitivity of cancer detection in this «gray zone» determination of % free PSA *i.e.* free PSA/total PSA ratio was introduced. In this study we report the development and analytical validation of an assay for quantitative determination of free prostate-specific antigen, fPSA.

MATERIAL AND METHODS: This assay is formulated as one step, two-site «sandwich» immunoradiometric assay. Specificity of this assay was achieved by using epitope-1-reactive anti-fPSA antibody as tracer antibody. Assay was calibrated against first international standard NIBSC Code 96/668.

RESULTS: Intra- and inter-assay coefficients of variation were 3.42–7.53% and 7.04–8.33%, respectively. Detection limit was determined as 0.08 µg/L. Measured concentrations of serially diluted serum samples were close to the calculated concentrations, with recovery ranging from 98.7–107.4%. Also, concentrations of fPSA determined by INEP IRMA-fPSA was in good correlation with those obtained by CIS FPSA-RIACT assay ($r=0.964$).

CONCLUSION: Analytical performance characteristics of fPSA assay speaks in favour of its use as a reliable tool in laboratory diagnostics relating to prostate diseases.