Multicenter Evaluation of a New Immunoassay for Intact PTH Measurement on the Elecsys® System 2010 and 1010

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SUMMARY

Background and Objective: The determination of parathyroid hormone (PTH) is of great clinical relevance in the assessment of calcium metabolic disorders. Although PTH was one of the first hormones measured by immunoassays, there are still many difficulties in its determination due to the low concentration of the hormone in blood and due to the heterogeneity of PTH resulting from different circulating hormone fragments. The aim of our multicenter-study was to evaluate the technical performance and the clinical validity of a new immunoassay for intact PTH measurement on the Elecsys® Systems 2010 and 1010.

Methods and Results: The multicenter evaluation was performed in 11 clinical laboratories. The Elecsys® PTH assay is a one step sandwich electrochemiluminescence immunoassay based upon the streptavidin-biotin technology. Two monoclonal antibodies are used in the assay providing detection of intact PTH. The imprecision study yielded within-run and between-days coefficients of variation of 3.1% -- 6.6% and 3.4% -- 15.6%, respectively using a three level control (PreciControl Bone, Roche Diagnostics) and human pool sera at two different concentrations (HS-low: 20 – 60 pg/ml, HS-high > 65 pg/ml). The analytical sensitivity calculated as the mean value plus 2 standard deviations of a within-run imprecision was below 2.70 pg/ml using zero calibrator matrix. Dilution linearity was observed up to 4890 pg/ml using zero calibrator matrix or human pool sera. Recoveries ranged between: 88% – 115%. Serum, EDTA- and heparin plasma were evaluated for PTH measurement. Due to a better analyte stability (48h at 21 °C, 3d at 4 °C) EDTA plasma was recommended for PTH measurement. Results of the Elecsys PTH immunoassay correlated well (r = 0.926 – 0.994) with three different immunoradiometric assays (N-tact® PTH SP, DiaSorin, Nichols AlleeGro® Intact PTH, Nichols Institute Diagnostics; ELSA-PTH, CisBio® International) and two different immunoluminometric assays (PTH-Intact-Immulite®, DPC Biermann; Nichols Advantage® Intact PTH, Nichols Institute Diagnostics) in technical and clinical method comparisons. The Passing/Bablok regression analysis yielded slopes of 0.692 – 1.729 and intercepts of -13.562 – 15.763 pg/ml. Deviations from slope 1 and intercept 0 were not unexpected due to differences in immunoassay standardization and probably due to the presence of different PTH fragments and a variable affinity of the used antibodies to these PTH fragments. Highly similar PTH concentration pattern of the Elecsys® immunoassay and the Quick-Intraoperative™ Intact PTH immunoassay (Nichols Institute Diagnostics) obtained from specimens taken intraoperatively support the applicability of the Elecsys® immunoassay to monitor the success of parathyroid resection. A reference range of 12.3 – 56.0 pg/ml calculated from PTH values of 43 apparently healthy individuals confirms reference limits published in the literature. The partition of collectives according to age showed, that individuals > 50 years have slightly higher PTH concentrations, independently of gender. This shift could be due to age itself or to an increased prevalence of individuals without obvious calcium metabolic disorders in this collective.

Conclusion: The Elecsys® PTH assay is a useful and reliable tool for determination of intact PTH. Our data support the intended use of the assay in clinical applications related to disorders of calcium metabolism.