EVALUATION OF THE TOSOH 1-84 INTACT PTH ASSAY IN AN INTEGRATED HIGH AUTOMATION CORE LAB PLATFORM

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BACKGROUND

Parathyroid hormone (PTH) secretion from parathyroid cells is regulated by action of the calcium on calcium-sensing receptor. Vitamin D metabolites and phosphorus have chronic indirect effect on PTH secretion via effects on PTH gene transcription or PTH mRNA stability. Measurements of the serum levels of PTH hormone allows for diagnosis and monitoring of several metabolic bone disorders. In last half century many assays for the measurements of PTH levels in the serum or plasma have been developed. It is important to understand characteristics of these assays to be able to make informed diagnostic conclusions from their results. The TOSOH AIA-PACK allow quantification of intact (1-84) PTH. The aim of that work was to evaluate the analytical performance of this new test.

MATERIALS and METHODS

By using two different TOSOH AIA 2000 analyzers connected with a Thermo EnGen automation, we evaluated the following analytical characteristics: within run and inter assays precision (CLSI EP-5A2), analytical and the functional sensitivity (CLSI EP-17), linearity (CLSI EP-6A), recovery (CLSI EP-6P). Finally, we evaluated the concordance with the assay previously adopted in our Laboratory (Siemens Immulyte 2000 1-84 intact PTH assay) in 67 hemodialysis patients.

RESULTS

Within run and inter assays precision did not exceeded 7% these data were reported in *Figure 1*. Analytical and functional sensitivity were respectively 0.9 and 2.5 pg/mL. The mean recovery was 92.0%. The method was found to be linear until the 1/10 dilution. As reported in *Figure 2* we observed a very good correlation of this assays with the method previously adopted in our Laboratory.

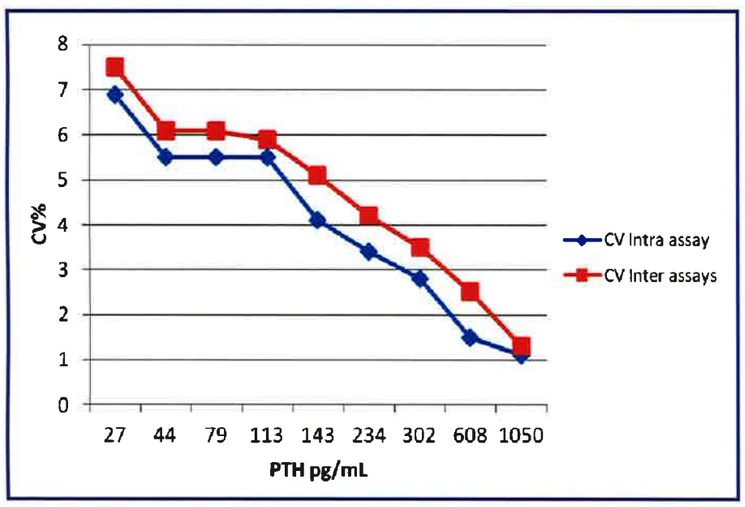

Figure 1: Imprecision Profile

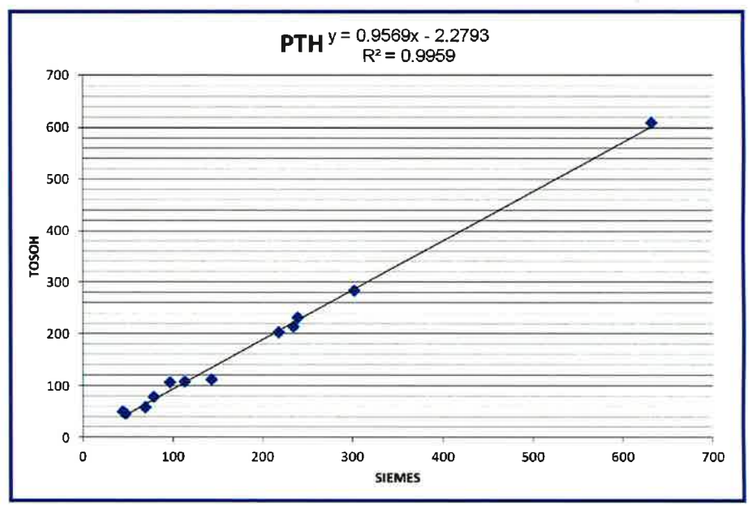

Figure 2: Methods correlation

CONCLUSIONS

An ideal PTH assay should possess high precision and accuracy along with a low degree of variation in repeated measurements. Unfortunately both first and second generation assays did not meet the criteria for an ideal assay. Realizing the shortcomings of the second generation PTH IMA assays, efforts were made to develop the next generation of assays that employ the detection antibody that has specificity for the first four aminoacids in the PTH molecule. These assays are called "third generation PTH IMA assays" as well as "intact PTH assays". The specificity of these assays was confirmed by their inability to detect synthetic PTH fragments lacking one or more N-terminal aminoacids. In this paper we evaluated the analytical performance of a 1-84 intact PTH assay supplied by TOSOH, this evaluation was performed by using two AIA 2000 analyzers connected, within a high automation core-lab area, with a Thermo EngGen pre-analytical and tracking station. In these conditions TOSOH AIA PACK Intact PTH demonstrated a series of remarkable analytical performances with an accuracy profile showing that the method is completely validated between 7 and 1050 pg/mL. We also observed, in a group of hemodialysis patients a very good correlation with our previous method.