PTH Assay, a new automated immunoassay for the
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Introduction: The Liaison 1-84 PTH allows the determination of (1-84) PTH without cross-reaction to the (7-84) fragment. It is one of the first automated ñ3rd generationò PTH immunoassay. Unlike the ñ2nd generationò or ñintactò PTH assays, the N-terminal antibody is specific for the first aminoacids of the peptide. The aim of that work was to evaluate the analytical performance of this new test. We also established the reference range of the parameter in a biologically well-defined healthy population.

Material and methods: On two different Liaison automates, we evaluated the precision with a modified protocol based on CLSI EP-5A2: twelve serum pools were assayed in triplicate once per day on five different days. We established the analytical and the functional sensitivity with a method adapted from CLSI EP-17. Linearity was evaluated based on CLSI EP-6A. Recovery was determined according to CLSI EP-6P. Finally, we evaluated the measurement uncertainty, accuracy and β-expectation limits. We settled the β-expectation tolerance limits with β=0.95 and considered the method as valid if each future measurements of the same level had a probability of 95% to fall in the ±20% accepted limits of accuracy. We selected 60 male and 118 female for our reference population using these variables: age >18 yo, levels of 25-OH vitamin D (25VTD) >32 ng/mL, calcium and phosphorous in the laboratory reference range and eGFR> 60 mL/min/1.73m² (estimated by the MDRD equation). All the subjects were Caucasian. We used the Kolmogornov-Smirnov test to check if the population was Gaussian.

Results: Analytical and functional sensitivity were respectively Ò0.7 and Ò2.2 pg/mL. Repeatability and intermediate precision did not exceed 8% in the validated range. The mean recovery was 94.0±3.4%. The method was found to be linear until the 1/10 dilution. Measurement uncertainty was comprised between 14 and 7.4%. The accuracy profile built with the predictive tolerance interval method shows that, on average, 95% of the future results that will be generated by this method will be included in the computed tolerance intervals of ±20% in the 4.3-1392 pg/mL studied range. Our selected population presented a mean 25VTD level of 41 ng/mL (Lowest:32; Highest: 93), a mean calcium of 2.32 mmol/L (Lowest:2.15 ï Highest: 2.52) and a mean age of 56 yo (Lowest:19; Highest: 89). There was no significant difference between men and women. The reference range observed in this population was 4.6 (90% CI: 3.4-5.9) ï 26.8 (90% CI: 25.6-28.0) pg/mL.

Conclusions: The Liaison 1-84 PTH is one of the first commercially available automated 3rd generation PTH assays. The analytical performances are remarkable, with an accuracy profile showing that the method is completely validated between 4.3 and 1392 pg/mL. We also established a reference range (4.6-26.8 pg/mL) on a very well biologically defined population.