ANALYTICAL EVALUATION OF AIA-PACK iPTH TOSOH ASSAY: DOES THIS METHOD FULFILL DIAGNOSTIC REQUIREMENTS?

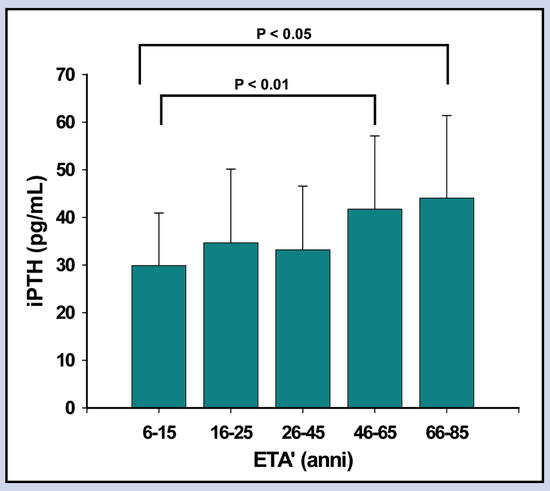
M. Bagnasco[1], P. Pedrazzi[2], L.C. Bottaro[2], M. Lodolini[3], L. Fazzuoli[1], F. Minuto[1], A.F. Radicioni[4], F.M. Lattanzio[5], P. Bellati[6]

1: Endocrinologia e Lab. Autoimmunità, Di.M.I., Univ. Genova, IRCCS AOU S.Martino-IST, Genova, Italy, 2: Lab. di analisi ASL 3, Genova, Italy, 3: Lab. Analisi Area Immunometria, Osp. Maggiore, Bologna, Italy, 4: Dip. Medicina Sperimentale, Univ. Roma La Sapiemza, Italy, 5: Lab. Patologia Clinica 2, Policlinico SS. Annunziata, Chieti, Italy, 6: TOSOH Bioscience, Mktg & Scient. Dep., Torino, Italy

BACKGROUND AND AIM OF THE STUDY

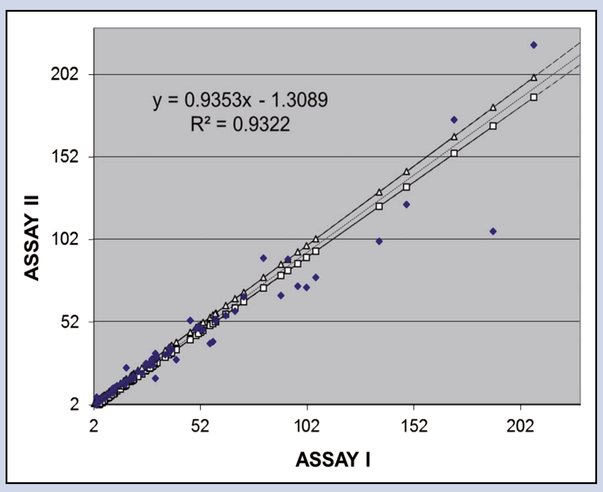
The use of Parathyroid hormone (PTH) assay has become widespread. A relationship between PTH levels and the outcone of chronic heart and renal diseases has been envisaged on the basis of a number of studies. Despite the attention has been recently focused on the assay of the «whole» PTH molecule, the majority of commercially available methods are still based on the use of «intact» molecule as the antigen (iPTH). We evaluated the analytical and clinical performances of TOSOH iPTH AIA-Pack (Tokyo, Japan) and compared it to other available methods (ELSA Cis-Bio, Cedex, France;ADVIA Centaur, Siemens, Germany; Immulite, Siemens, Germany; Liaison, Diasorin, Italy).

PTH Concentration in Different Age Groups



AGE DEPENDENCE: 149 samples from healthy individuals of both sexes in different age groups were evaluated, showing significantly lower values in < 15 yrs children with respect to adults.

Dilution Test

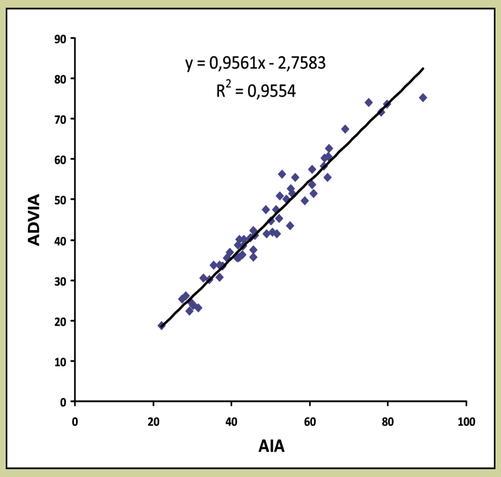


DILUTION TEST: 96 dilution tests per day peformed on 2 days with 5 sera from patients with primary hyperparathyroidism showed linearity of results between 290 and 1 pg/ml (1:2 to 1:64 x Z2-dilutions)

COMPARISON OF AIA WITH OTHER COMMERCIAL ASSAYS

AIA vs ADVIA

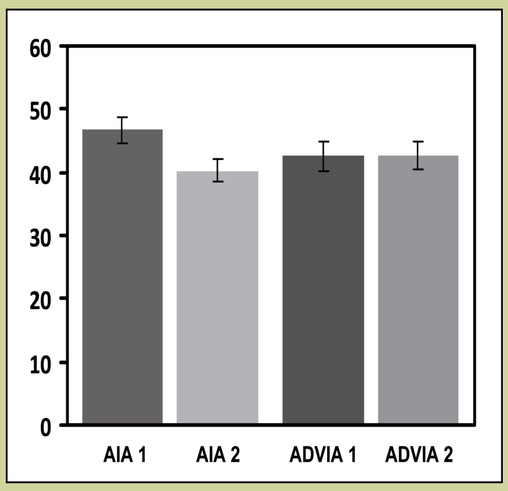
Fresh Plasma



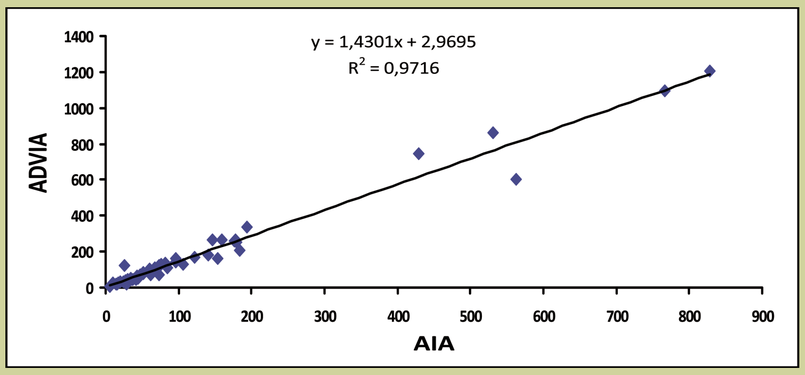
(AIA vs. ADVIA). Bland & Altman analysis: 11.5% AIA overestimation of borderline significance (CL -2.5-+25.4%) concentration-dependent (R2 = 0.166, Y= -0.098x + 10.39)

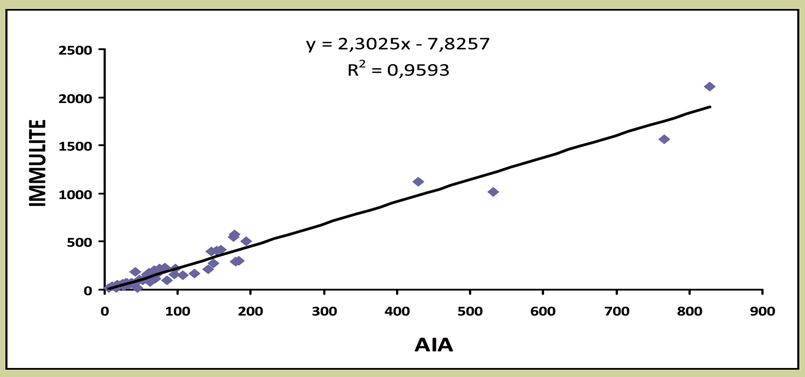
Fresh (1) vs frozen (2) plasma samples:

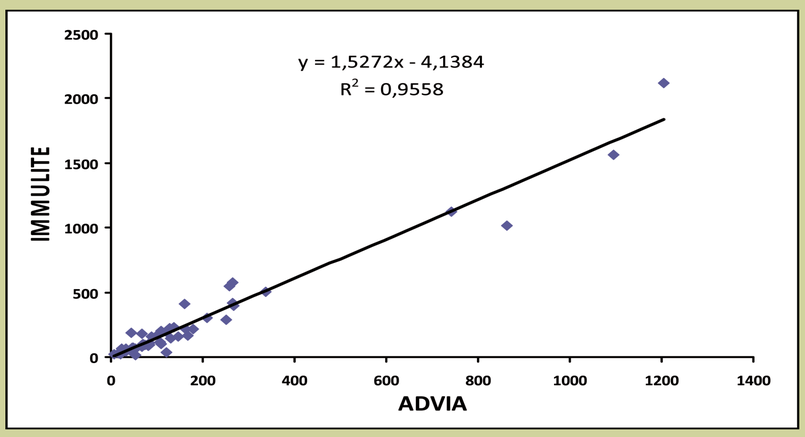
Slight AIA reduction, no modifications with ADVIA



Frozen Plasma

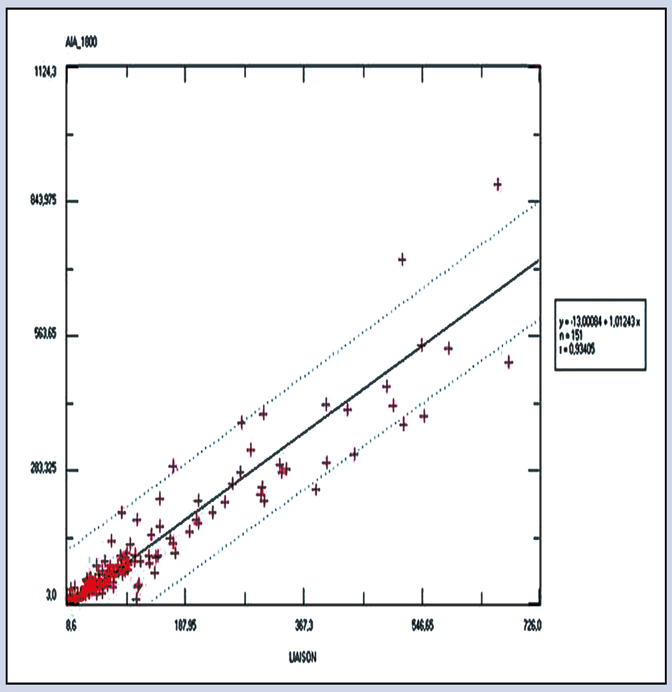




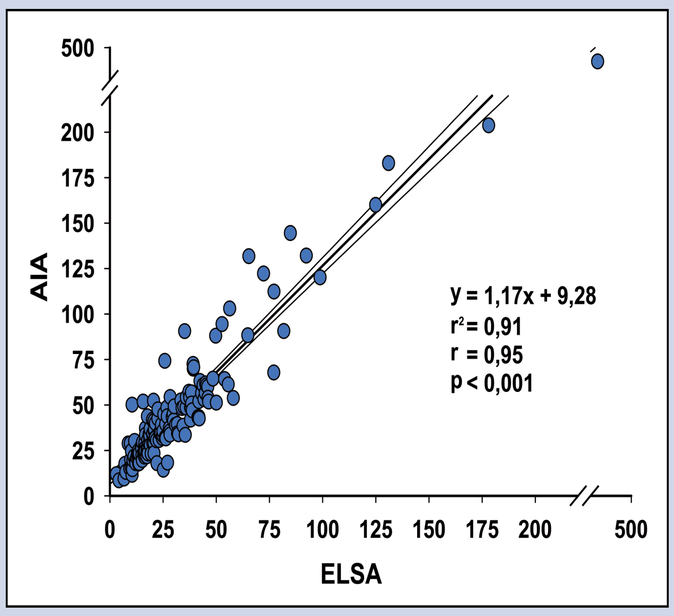


ADVIA overestimation vs. AIA, mean 36.3% (CL -6.1-78.8%). Linear Regression Analysis. R2 0.9716, y = 1.4301x + 2.9695. Immulite overestimation vs. AIA, mean 68.1% (CL 2.5-34%); Linear Regression Analysis R2 0.9593, y = 2.3025x -7.8257. Immulite overestimation vs. ADVIA , mean 34.3% (CL 111.9 – 43%); Linear Regression Analysis R2 0.9558, y = 1.5272x – 4.1384

AIA vs LIAISON



AIA vs ELSA



CONCLUSIONS

A fair overall correlation among the methods was observed, although variable systematic over- or underestimation biases exist, partially dependent upo the type of sample (serum,/plasma, or forzen/thawed). A good precision of the TOSOH AIA-Pack method has been demonstrated at different PTH concentrations by dilution test. An increase of iPTH values in normal subjects with age is apparent, and should be taken into account.