Analytical evaluation of a new fully automated immunoassay for the quantification of 1,25-dihydroxyvitamin D

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Background

- Quantification of 1,25-dihydroxyvitamin D ($1,25(OH)_2D$) remains challenging because of low circulating concentrations and potent cross-reactivities with steroid-like structures.
- Most of the commonly used assays for $1,25(OH)_2D$ testing are still based on radioimmunoassay (RIA) format with preliminary extraction.
- The analytical performances and the turnaround time of analysis (TAT) for these assays are limited.
- A novel fully automated assay for $1,25(OH)_2D$ testing has emerged.
- The aim of our study was to evaluate the analytical performances of this $1,25(OH)_2D$ automated immunoassay.

Methods

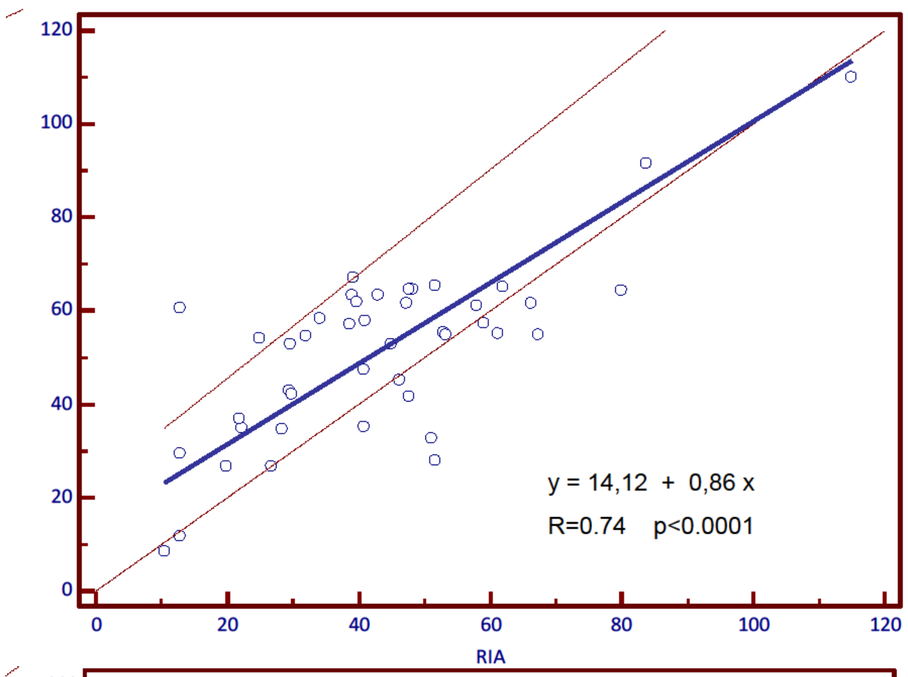
The evaluated method was the LIAISON® XL $1,25(OH)_2D$ assay (DiaSorin, Saluggia, Italy), a fully automated immunoassay that uses a recombinant fusion protein for capturing $1,25(OH)_2D$ [1]. The limit of detection was determined using the Ancillary reagent as blank. Within-run imprecision was determined by 4 replicates measurement of four self-prepared pool sera in a single run. Between-run imprecision was determined using two self-prepared pool sera and the two levels of control provided by the manufacturer. Method comparison was performed with our routine RIA method (n=43) and with a reference liquid chromatography-tandem mass spectrometry (LC-MS/MS) method (n=18) [2] through Passing-Bablok regression analysis and Bland-Altman plot.

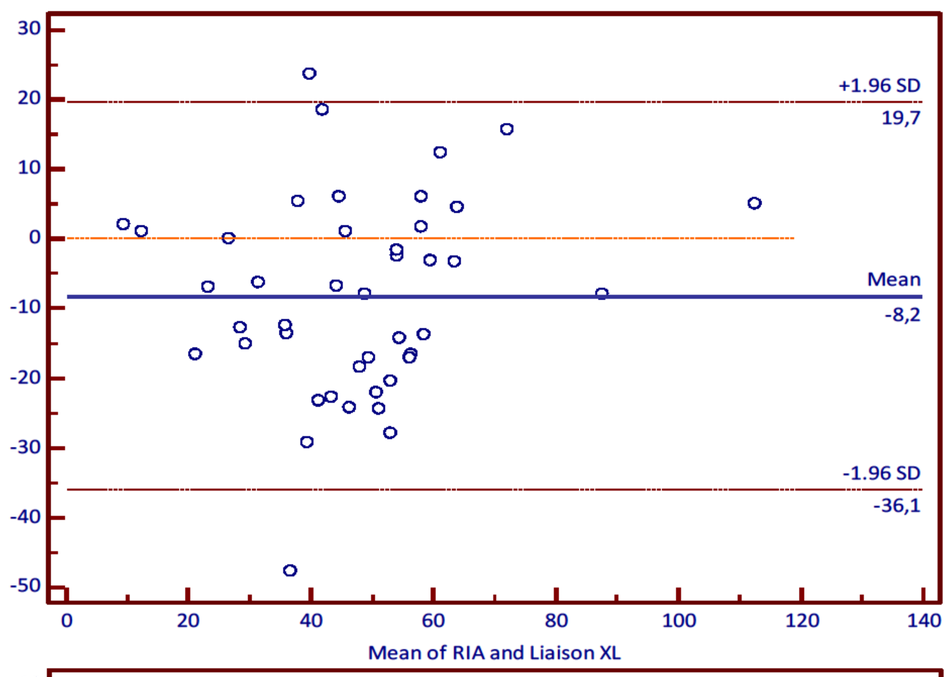
Results

Intra-assay precision	Mean, pg/ml	SD, pg/ml	CV, %
Level 1 (n=4)	6.71	0.17	2.55
Level 2 (n=4)	12.98	0.48	3.69
Level 3 (n=4)	16.73	0.50	2.98
Level 4 (n=4)	19.68	0.87	4.44

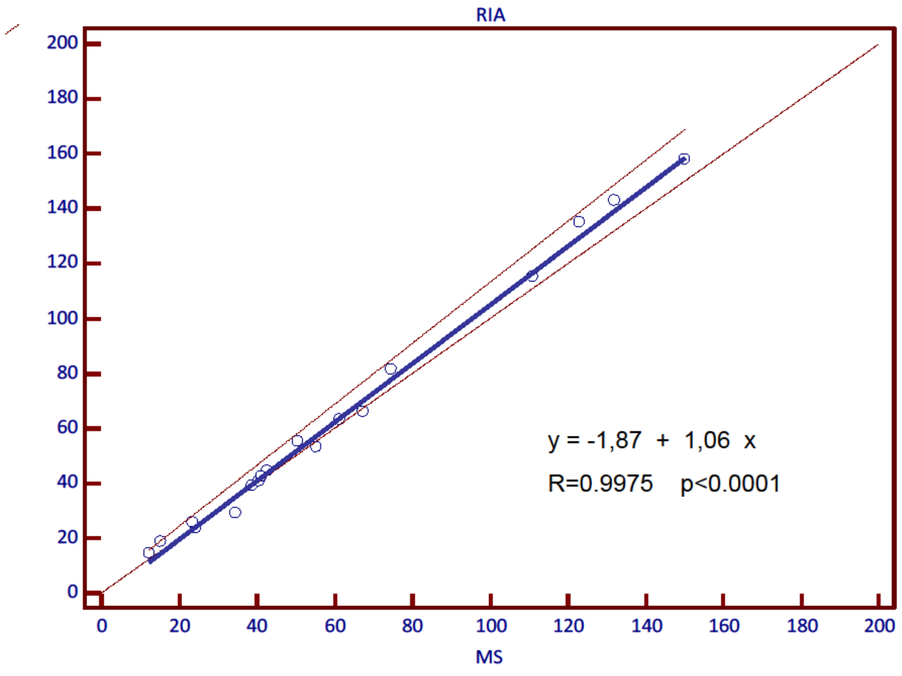
Inter-assay precision	Mean, pg/ml	SD, pg/ml	CV, %
Pool 1 (n=10)	27.52	1.82	6.61
Pool 2 (n=10)	90.45	5.07	5.60
Control 1 (n=28)	25.42	3.32	13.06
Control 2 (n=28)	101.09	9.44	9.33

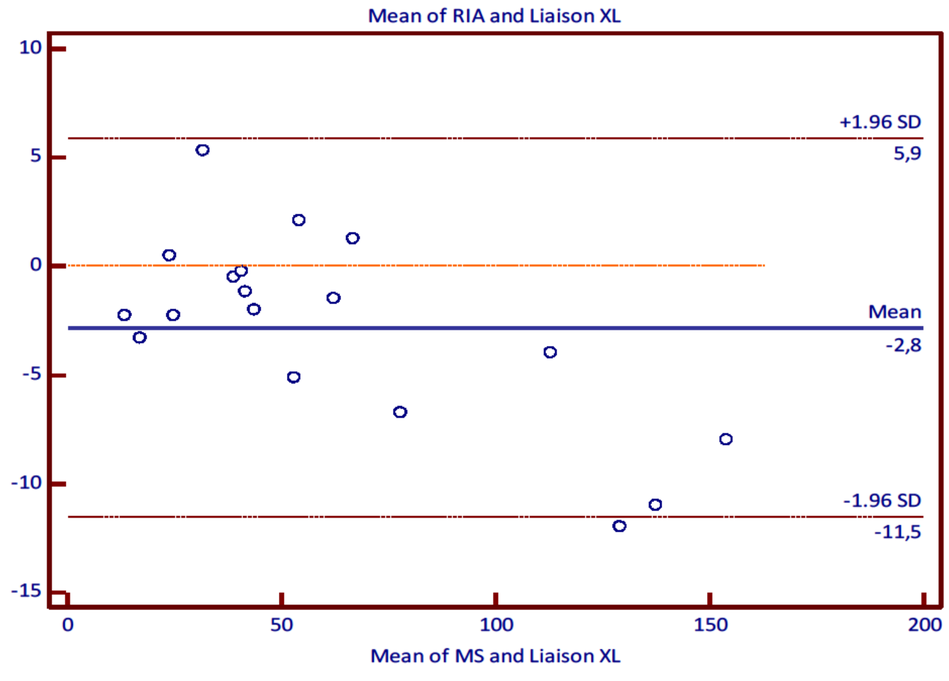
Comparison between the Liaison® XL automated immunoassay and the RIA method through Passing-Bablok regression analysis (left) and through Bland-Altman plot (right).





Comparison between the Liaison® XL automated immunoassay and the LC-MS/MS method through Passing-Bablok regression analysis (left) and through Bland-Altman plot (right).





Conclusions

- The LIAISON® XL $1,25(OH)_2D$ automated assay demonstrated superior analytical performances in comparison to RIA method with the potential of shorter TAT.
- Furthermore, we demonstrated a strong agreement between this $1,25(OH)_2D$ automated assay and a reference LC-MS/MS method.

References:

[1] van Helden J, Weiskirchen R., Experience with the first fully automated chemiluminescence immunoassay for the quantification of 1α, 25-dihydroxy-vitamin D. Clin Chem Lab Med. 2015 Apr 1;53(5):761-70.
[2] Strathmann FG, Laha TJ, Hoofnagle AN. Quantification of 1α,25-dihydroxy vitamin D by immunoextraction and liquid chromatography-tandem mass spectrometry Clin Chem. 2011 Sep;57(9):1279-85.

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Calcium, vitamin D and bone

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