Evaluation of the LIAISON® 25 OH Vitamin D TOTAL Assay on the new LIAISON® XL

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INTRODUCTION

Vitamin D has been known for decades for its critical role in increasing the efficiency of dietary calcium absorption and preventing rickets in children. However, recent research has uncovered other important relationships between vitamin D and bone health as well as new information on its pleiotropic action. These new evidences have fuelled the global demand for 25(OH)D testing. Clinical laboratories are under pressured to seek automated reliable platforms for 25-OH D analysis to keep up with the demanded volume. Recently, DiaSorin (Stillwater, MN) launched a new immuno-assay analyzer called Liaison XL. This analyzer presents some interesting features compared to the former Liaison. Nevertheless, according to the ISO 15189 Guideline, we needed to validate the 25-OH Vitamin D assay prior to use it in our daily routine.

MATERIALS AND METHODS

We evaluated the precision with a modified protocol based on CLSI EP-5A2: 6 serum pools were assayed in three replicates per day on five different days. We established the functional sensitivity and the accuracy profile of the method. Finally, we compared the results obtained with our Liaison on 201 patients spanning the whole range of measurement, studied the lot to lot variation, on 118 patients and two lots.

RESULTS

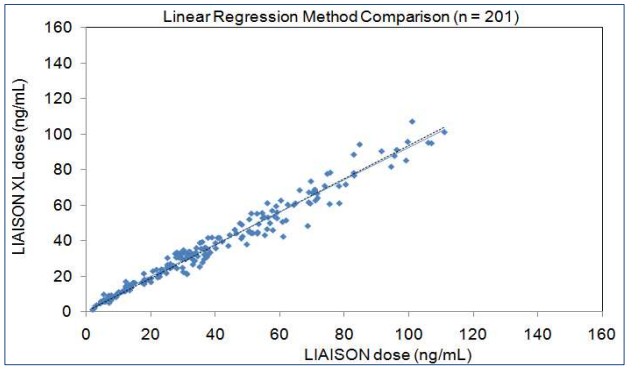

Figure 1 – Method comparison LIAISON® vs. LIAISON® XL
The regression equation between the two methods is: Liaison XL = 0.92x Liaison + 1.2).

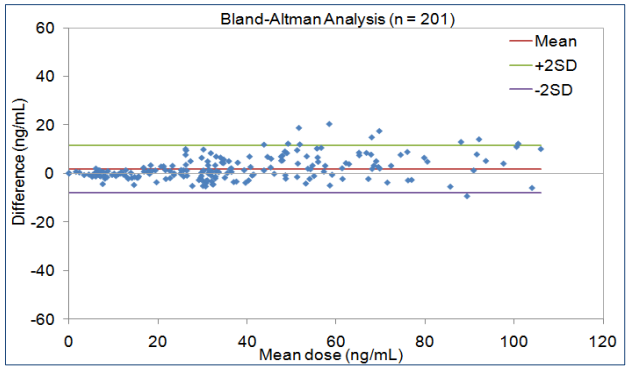

Figure 2 - Instrument bias LIAISON® vs. LIAISON® XL
The Bland Altman plot shows a good agreement between the 2 instruments with a mean bias at 2.5 ±6.2 ng/mL.

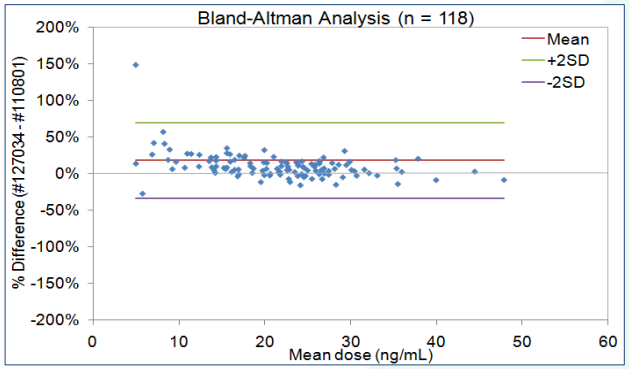

Figure 3 – Lot variation LIAISON® XL
The mean difference between the two lots was 6.6% and the Bland Altman plot shows a mean difference of 1.4 ±2.3 ng/mL.

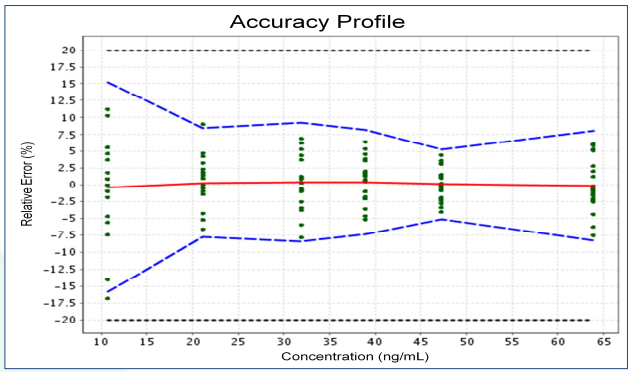

Figure 4 – Accuracy Profile LIAISON® XL
The accuracy profile built with the predictive tolerance interval method shows that, on average, 95% of the future results that will be generated by this method will be included in the computed tolerance intervals of ±20% in the 10.1-63.9ng/mL studied range.

The Limit of Quantitation (LOQ) was established at 2.5 ng/mL

Sample No.	Mean (ng/mL)	Repeatability (CV %)	Intermediate precision (CV %)
1	10,7	6,47	7,08
2	21,1	3,74	3,78
3	31,9	4,01	4,12
4	38,9	2,74	3,4
5	47,2	2,41	2,41
6	63,9	3,82	3,82

Table 1 – Repeatability and Intermediate precision LIAISON® XL
Repeatability and intermediate precision were <5% from 21 to 69 ng/mL. At 10 ng/mL, they were respectively of 6.5 and 7.1%.

CONCLUSION

DiaSorin Liaison XL is a friendly and easy-to-use instrument that possesses a lot of interesting new features compared to the former Liaison. From an analytical point of view, the performances of this new instrument are really improved. Nevertheless, a better lot-to-lot consistency could be expected.

AACC 2012, Los Angeles 15 – 19 July