Analytical and clinical evaluation of the new Fujirebio Lumipulse® G sandwich assay for 25(OH)-vitamin D

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INTRODUCTION: Recently, Fujirebio launched on the LUMIPULSE G instrument a non-competitive sandwich assay for 25(OH)-vitamin D [25(OH)D]. This sandwich method is based on antimetatype monoclonal antibodies against a hapten-antibody immunocomplex using an *ex vivo* antibody development system. In this study, we report on the analytical and clinical evaluation of the Fujirebio Lumipulse G 25-OH Vitamin D assay.

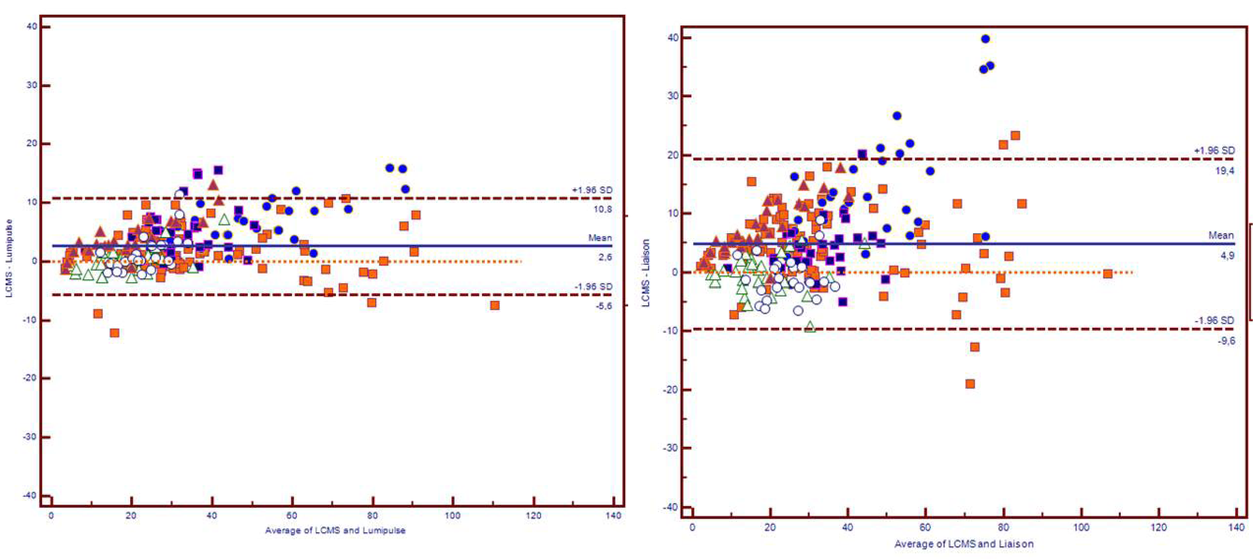

Figure 1. Passing-Bablok regression analyses for all immunoassay methods tested vs. a VDSP-certified LC-MS/MS

MATERIAL AND METHODS: The analytical evaluation included precision, recovery, limit of quantification, as well as 25(OH)D2 and C3-epimer recovery. For the clinical evaluation, method comparisons of the new Fujirebio and three commercially available automated immunoassays against a VDSP-traceable LC-MS/MS was performed on serum samples obtained from healthy Caucasians (n=100) and Africans, osteoporotic, hemodialyzed and intensive care patients and 3rd trimester pregnant women (n=30).

RESULTS: Intra-assay CV ranged from 12.1% at 9.6 ng/mL to 2.1% at 103.7 ng/mL and inter-assay CV ranged from 16.2 to 3.7 % at the same concentrations, respectively. Measurement uncertainty, with a probability of 95%, were 33.1% and 7.6%, respectively. LOQ was found to be at 4.6 ng/mL. Mean (95% CI) 25(OH)D2 recovery was 77% (74-81) and no cross-reactivity was observed with C3-epimer. Both results were obtained on native, non-spiked samples.

The Lumipulse G assay presented interesting analytical features and showed excellent correlation to the LC-MS/MS results (y = 1.00x-1.35 ng/mL), as obtained in healthy Caucasian individuals. In the other special populations, Lumipulse G presented a concordance with LC-MS/MS that was generally higher than competitors. (Figure 1 & Table 1)

Table 1. Concordance analyses for all immunoassay methods tested vs. a VDSP-certified LC-MS/MS

		Healthy	African Healthy	Hemo-dialysis	3rd trim pregnant ♀	ICU patients	Osteo-porosis
Fujirebio Lumipulse	**r - C_b**	0.98 – 1.00	0.92 – 0.93	0.99 – 0.92	0.99 – 0.92	0.98 – 0.99	0.89 – 0.87
	CCC	0.98	0.85	0.91	0.91	0.97	0.77
DiaSorin Liaison	**r - C_b**	0.97 – 0.99	0.86 – 0.99	0.88 – 0.67	0.97 – 0.77	0.94 – 1.00	0.89 – 0.91
	CCC	0.96	0.85	0.60	0.75	0.94	0.81
IDS iSYS	**r - C_b**	0.94 – 0.96	0.85 – 0.73	0.95 – 0.55	0.94 – 0.72	0.95 – 0.92	0.87 – 1.00
	CCC	0.90	0.62	0.53	0.68	0.88	0.87
Roche Elecsys	**r - C_b**	0.90 – 0.98	0.76 – 0.72	0.89 – 0.91	0.95 – 0.99	0.94 – 0.93	0.77 – 0.96
	CCC	0.87	0.54	0.80	0.95	0.87	0.74

STATISTICAL ANALYSIS: MedCalc software (Oostende, Belgium) was used for the statistical comparisons and allowed to perform the Passing-Bablok regressions and concordance correlation coefficient (CCC). The CCC evaluates the degree to which pairs of observations fall on the 45° line through the origin. It contains a measurement of precision "r" and accuracy C_b and is calculated as CCC = r C_b, where r is the Pearson correlation coefficient (which measures how far each observation deviates from the best-fit line and thus the precision), and C_b is a bias correction factor that measures how far the best-fit line deviates from the 45° line through the origin, and is thus a measure of accuracy. CCC result can be interpreted as follows: poor (<0.90), moderate (0.90-0.95), substantial (0.95-0.99) and almost perfect (>0.99).

CONCLUSION: The Fujirebio Lumipulse G 25-OH Vitamin D assay presented interesting analytical features and showed excellent correlation to LC-MS/MS results in addition to the relatively good performance on special groups compared to other automated assays. The new assay is therefore considered suitable for assessment of vitamin D status in clinical routine.