

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

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Presenter Disclosure Information

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

I will not discuss off label use or investigational use in my presentation.

I have a financial relationship to disclose:

- Receiving an honoraria payment from DiaSorin to provide this presentation.

Workload on the Liaison XL at CHU de Liège

- 3rd generation PTH ~ 22.000 tests/year
- 25(OH)-vitamin D ~ 45.000 tests/year
- Calcitonin ~ 5.000 tests/year
- Bone-ALP ~ 5.000 tests/year

All tests accredited vs. ISO 15.189

Validation of the 25(OH)D on the Liaison XL

Validation procedure

- Precision (modified protocol based on CLSI EP-5A2: 6 serum pools were assayed in three replicates per day on five different days)
- Functional sensitivity
- Accuracy profile
- Lot to lot variability
- Method comparison:
 - with Liaison
 - with LCMS/MS (Perkin Elmer)
 - with Architect, Centaur, iSYS and Elecsys

Results

Precision

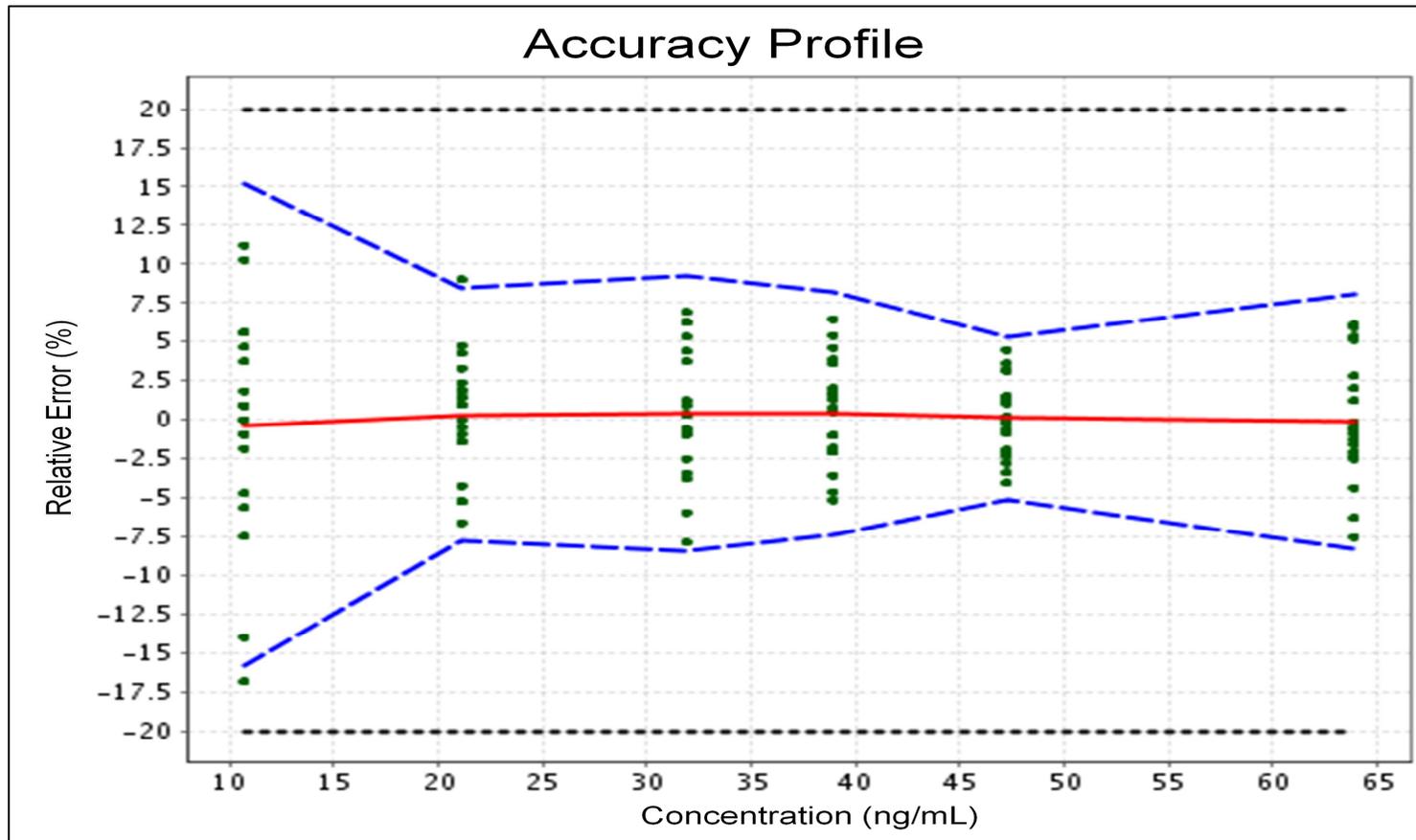
Sample No.	Mean, ng/mL (nmol/L)	Repeatability (CV %)	Intermediate precision (CV %)
1	10,7 (27)	6,5	7,1
2	21,1 (53)	3,7	3,8
3	31,9 (80)	4,0	4,1
4	38,9 (97)	2,7	3,4
5	47,2 (118)	2,4	2,4
6	63,9 (160)	3,8	3,8

Limit of quantification

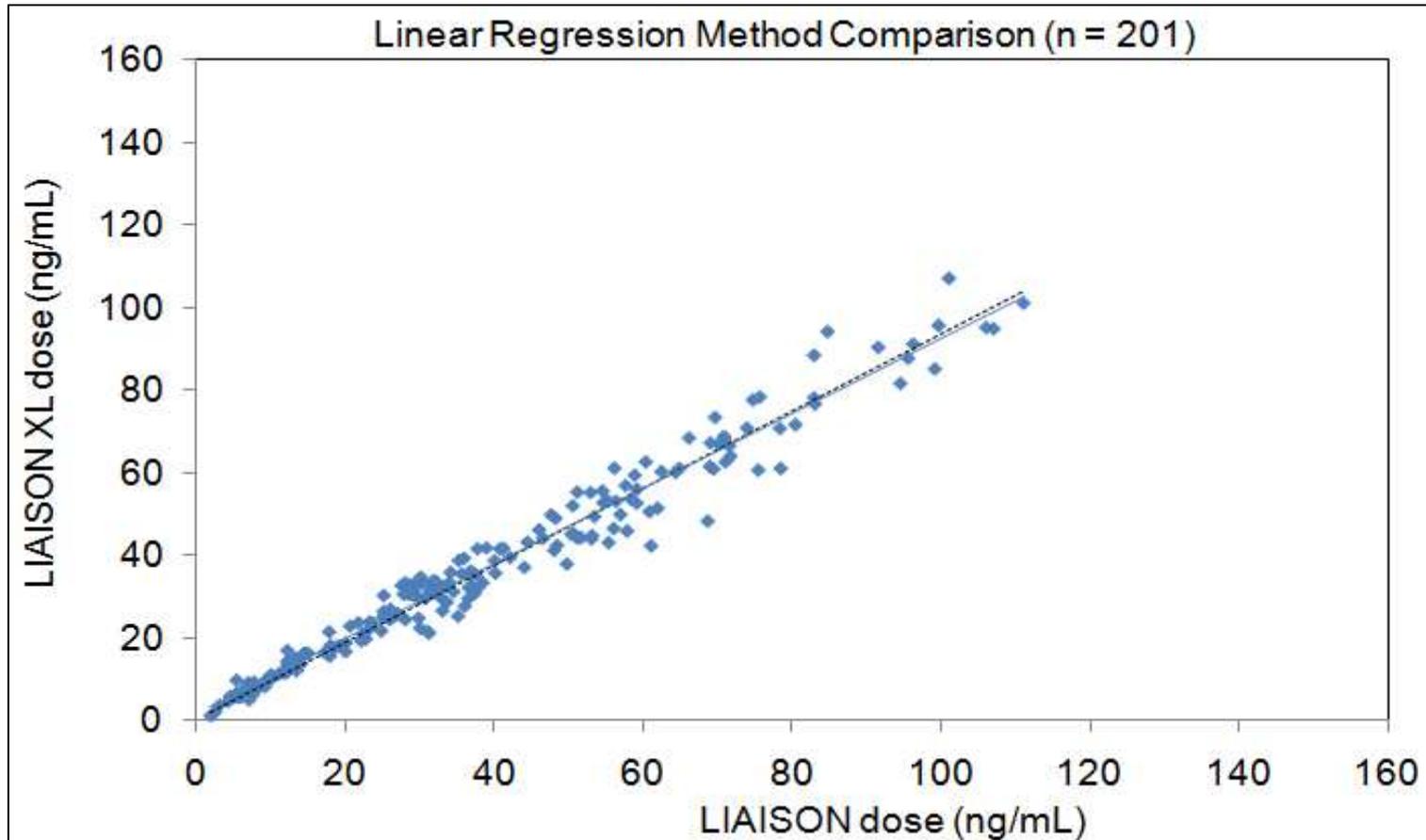
2.5 ng/mL

6.25 nmol/L

Accuracy profile

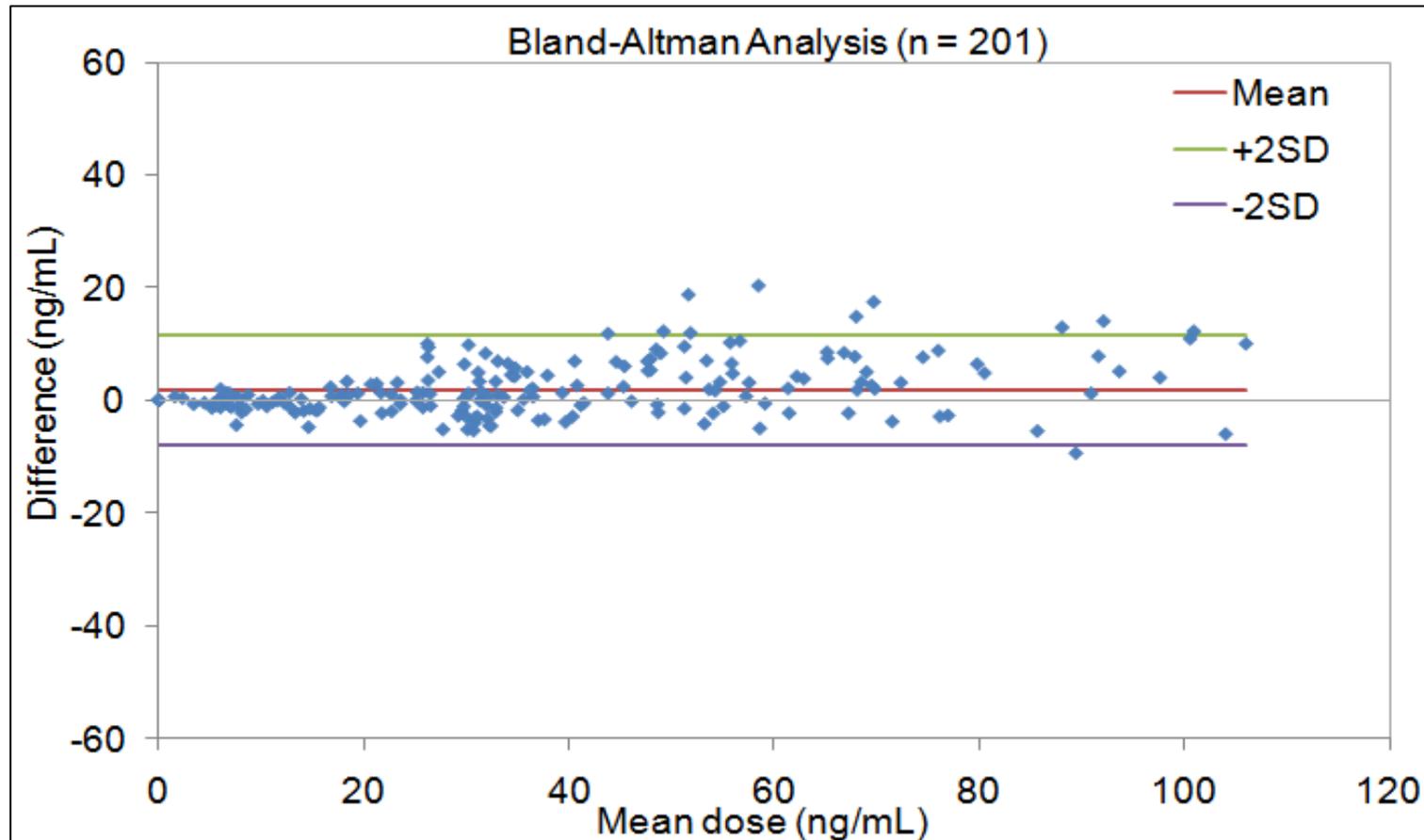


Comparison with the Liaison

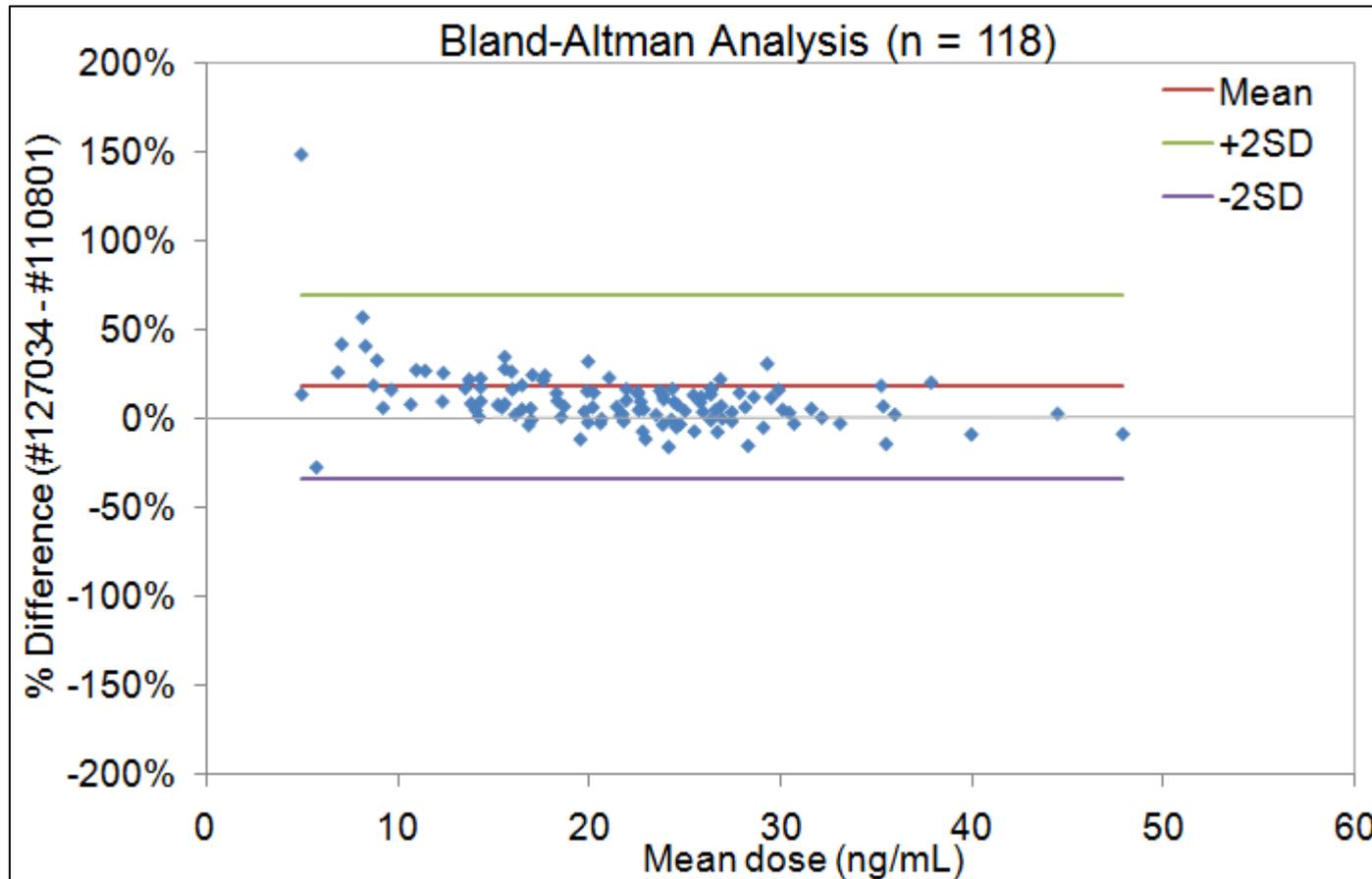


$$\text{Liaison XL} = 0.92x \text{ Liaison} + 1.2$$

Comparison with the Liaison



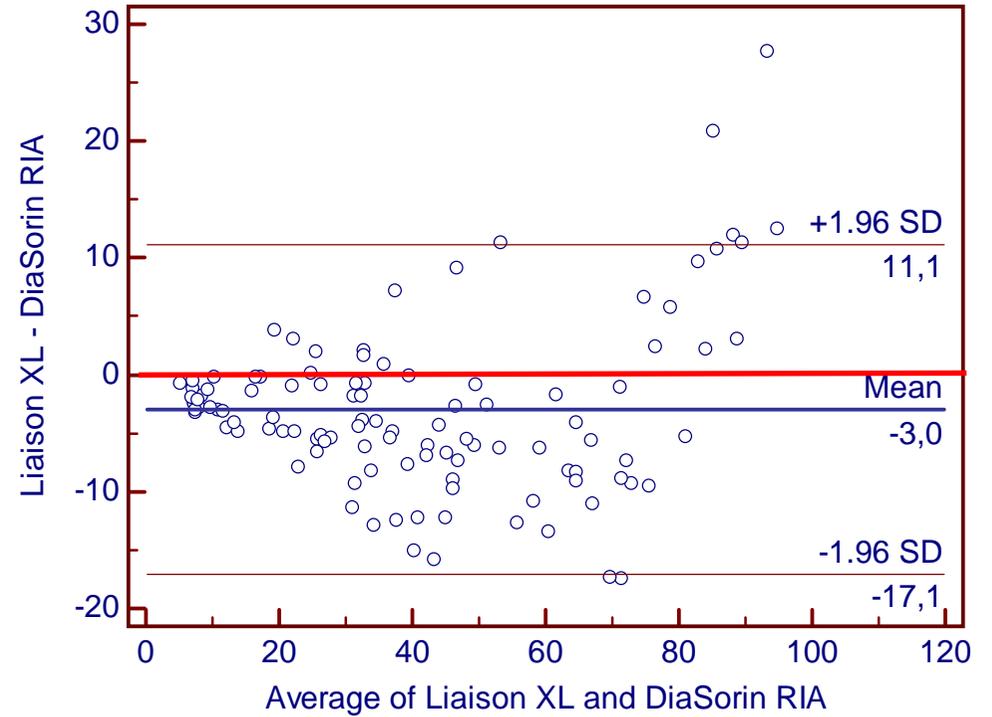
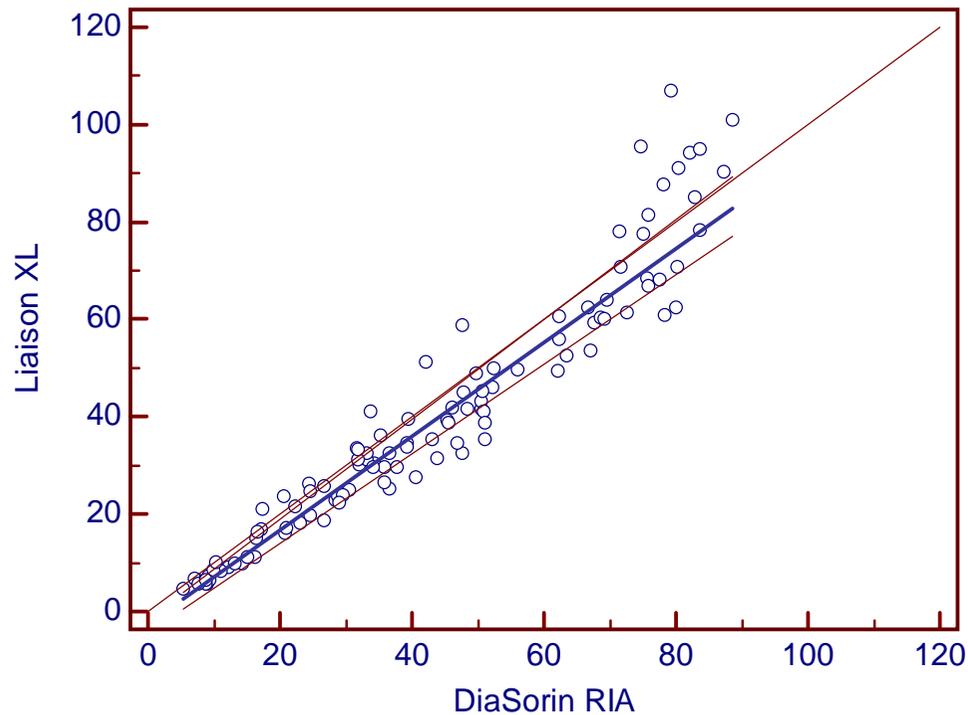
Lot-to-lot variation



Comparison with other methods

DiaSorin RIA

$$\text{Liaison XL} = 0,96 \times \text{DiaSorin RIA} - 2,6$$



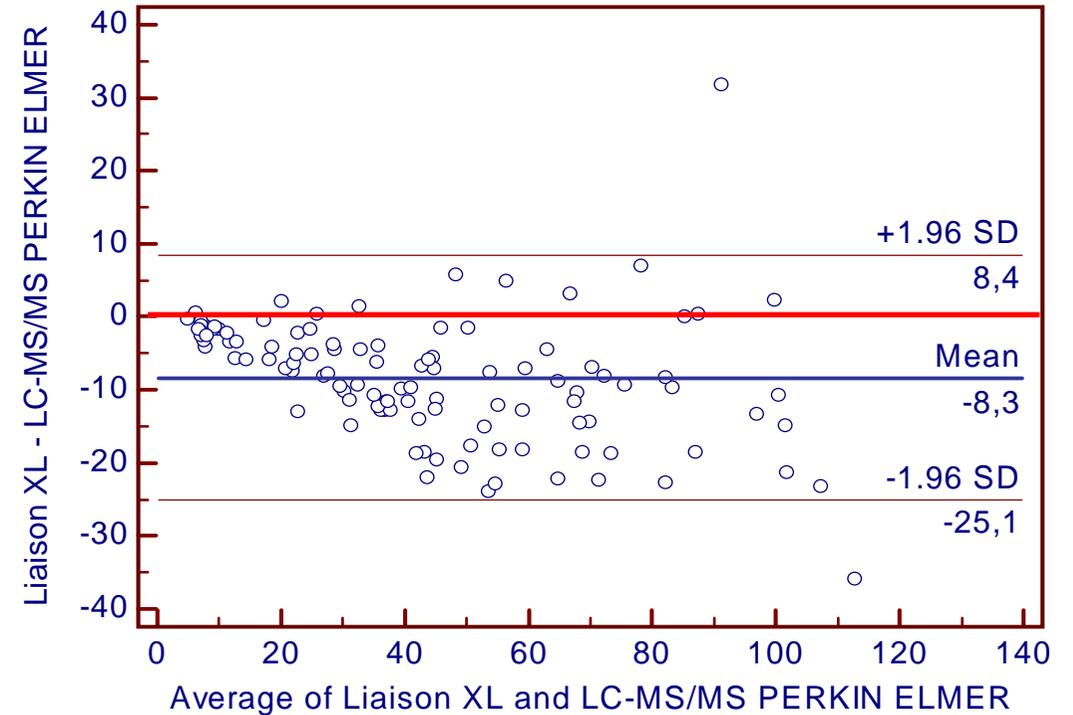
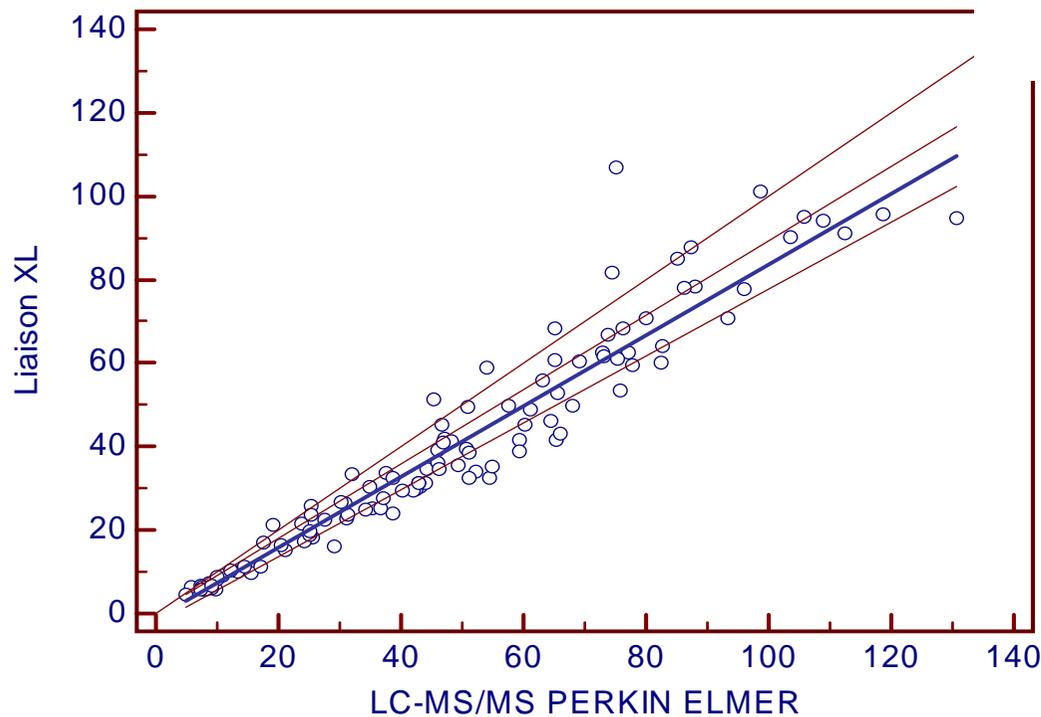
Intercept A	-2,6
95% CI	-4,5 to -1,6
Proportional differences	
Slope B	0,96
95% CI	0,92 to 1,03

Significant systematic difference

No significant proportional difference

LC-MS/MS with PerkinElmer kit

Liaison XL = 0,85 x LCMS/MS PE - 1,24



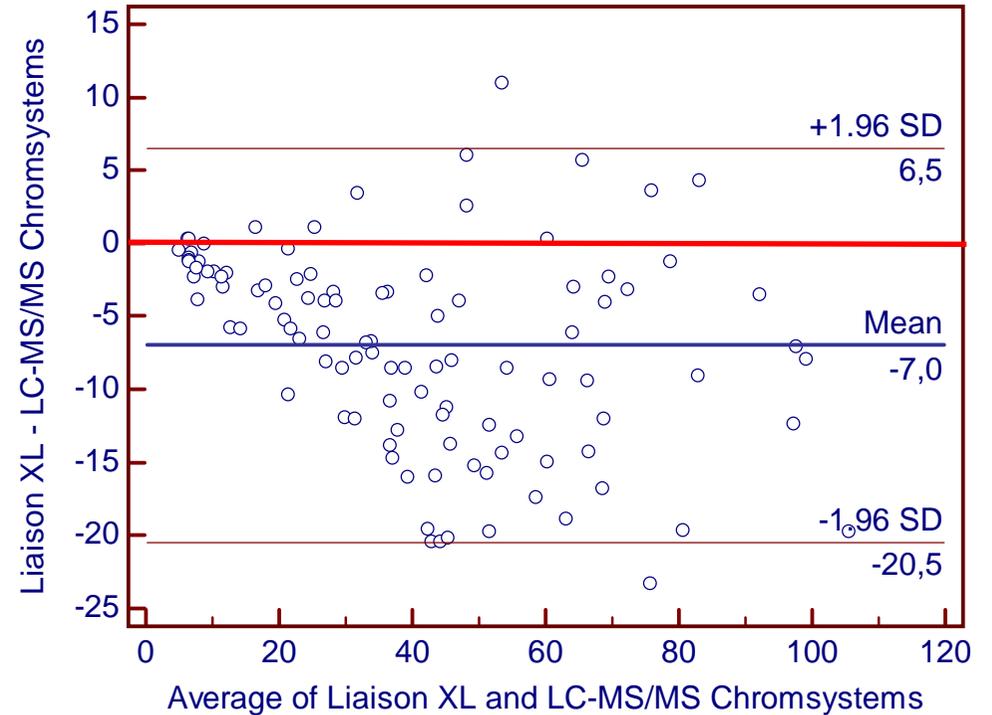
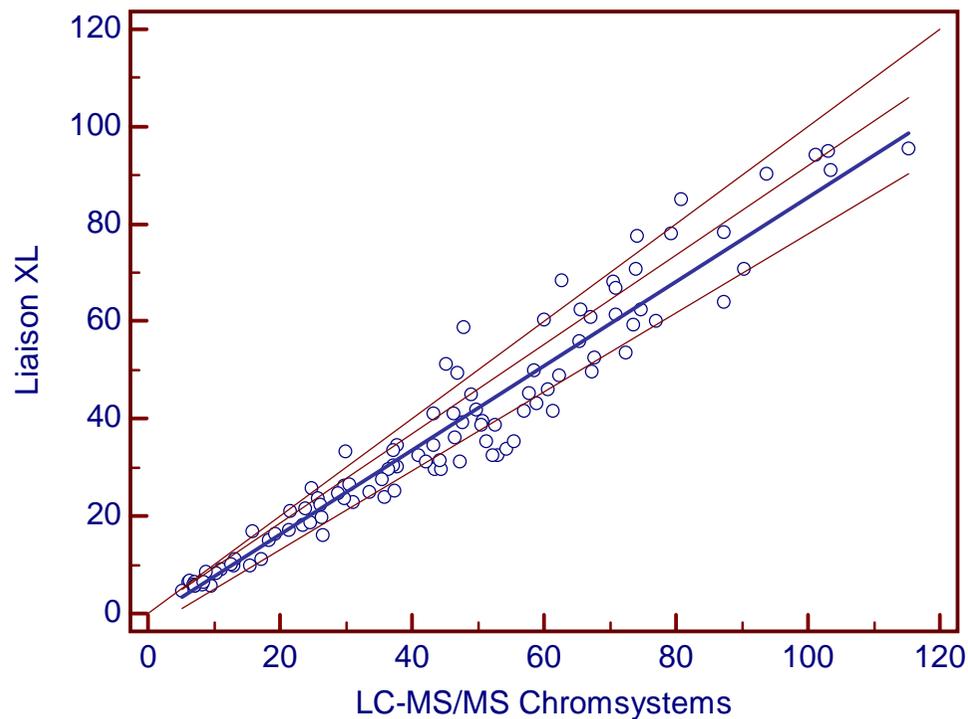
Intercept A	-1,24
95% CI	-2,5 to 0,09
Proportional differences	
Slope B	0,85
95% CI	0,80 to 0,89

No significant systematic difference

Significant proportional difference

LC-MS/MS with Chromsystems kit

$$\text{Liaison XL} = 0,86 \times \text{LCMS/MS CS} - 0,90$$



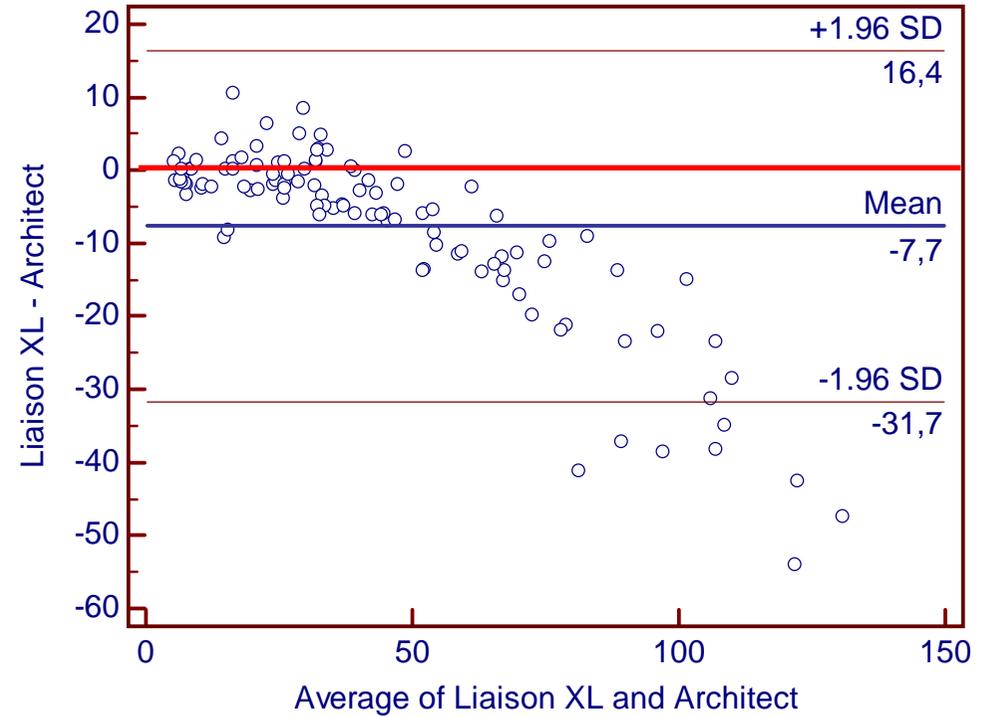
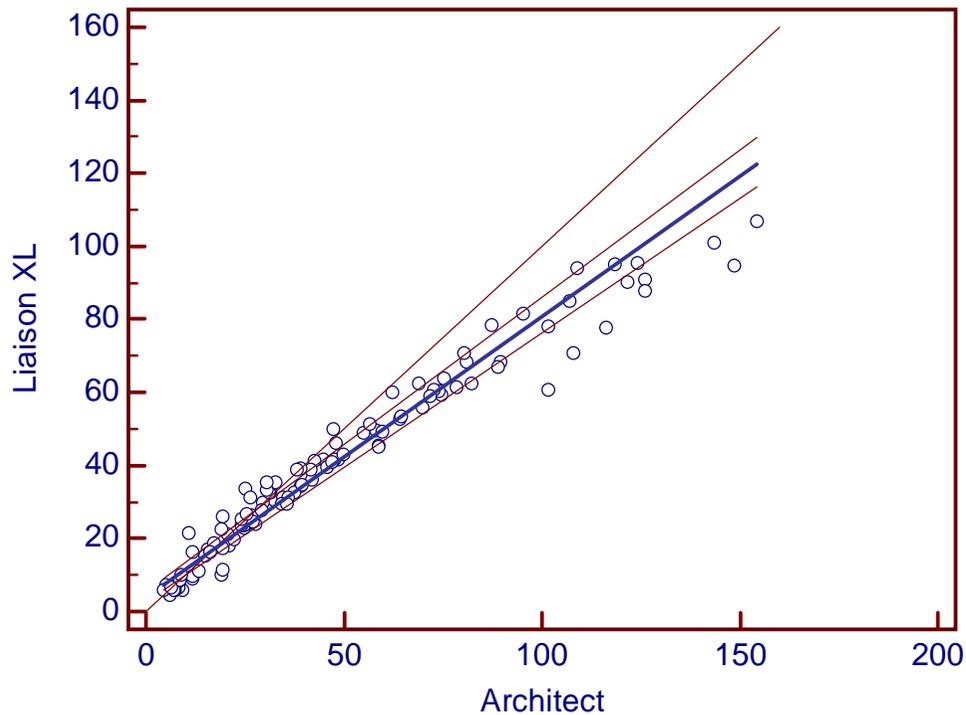
Intercept A	-0,90
95% CI	-3,14 to 0,19
Proportional differences	
Slope B	0,86
95% CI	0,81 to 0,92

No significant systematic difference

Significant proportional difference

Abbott Architect

$$\text{Liaison XL} = 0,77 \times \text{Architect} + 3,9$$



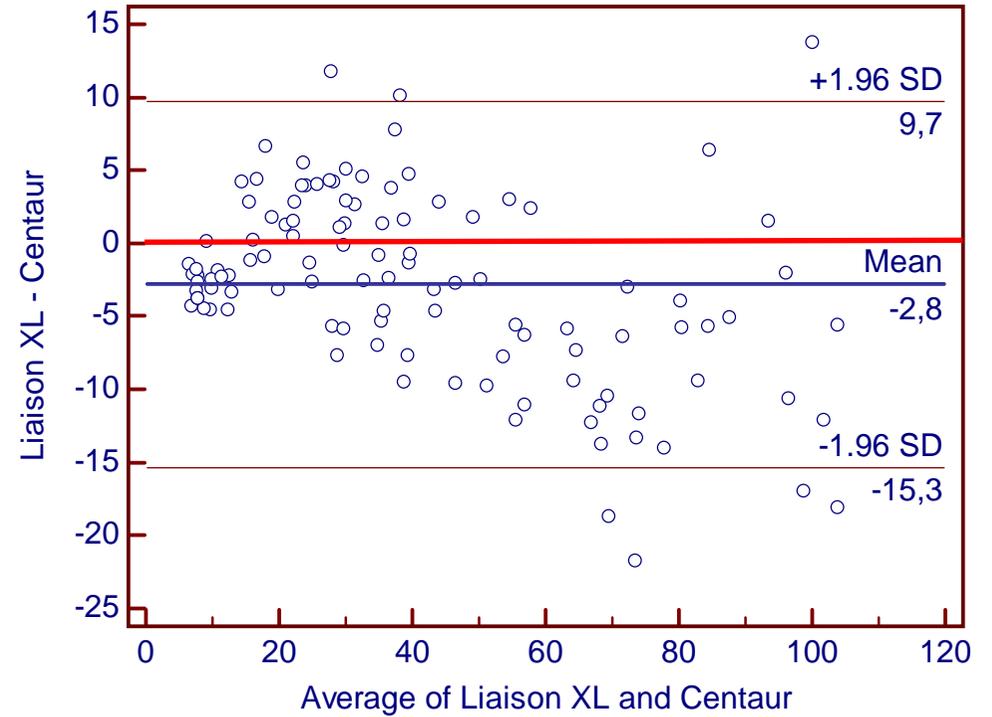
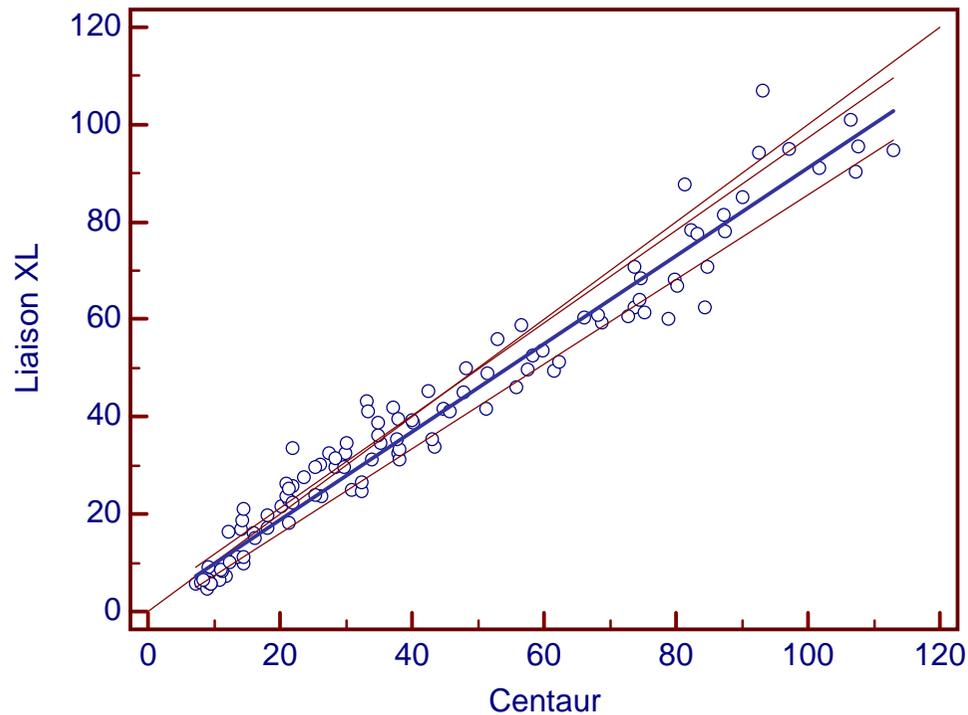
Intercept A	3,9
95% CI	2,7 to 5,4
Proportional differences	
Slope B	0,77
95% CI	0,74 to 0,81

Significant systematic difference

Significant proportional difference

Siemens Centaur

$$\text{Liaison XL} = 0,91 \times \text{Centaur} + 0,70$$



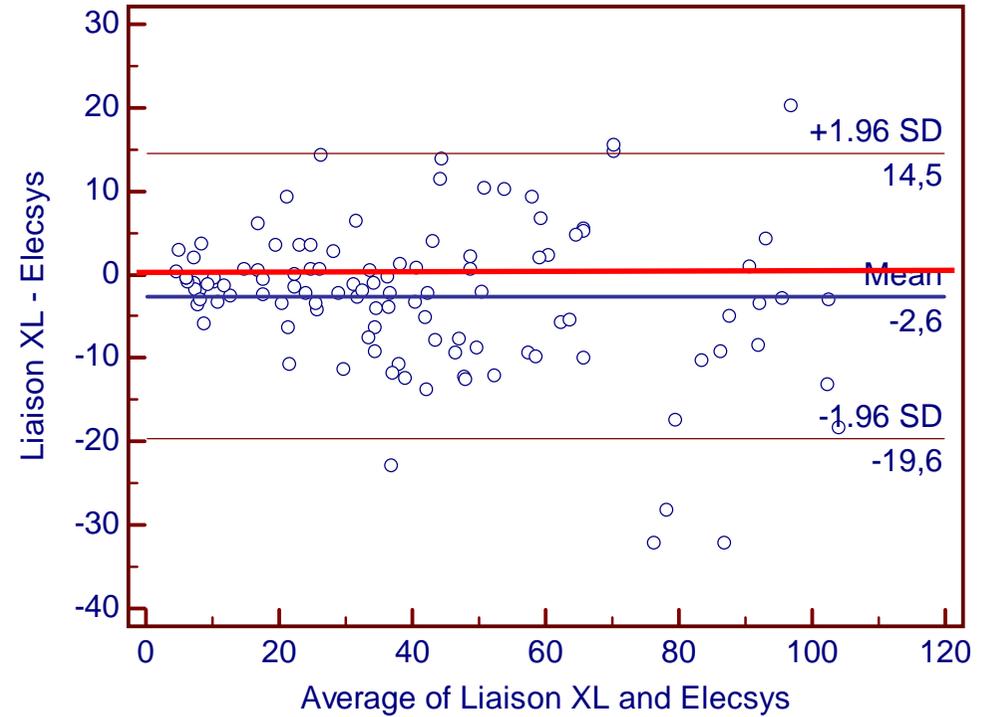
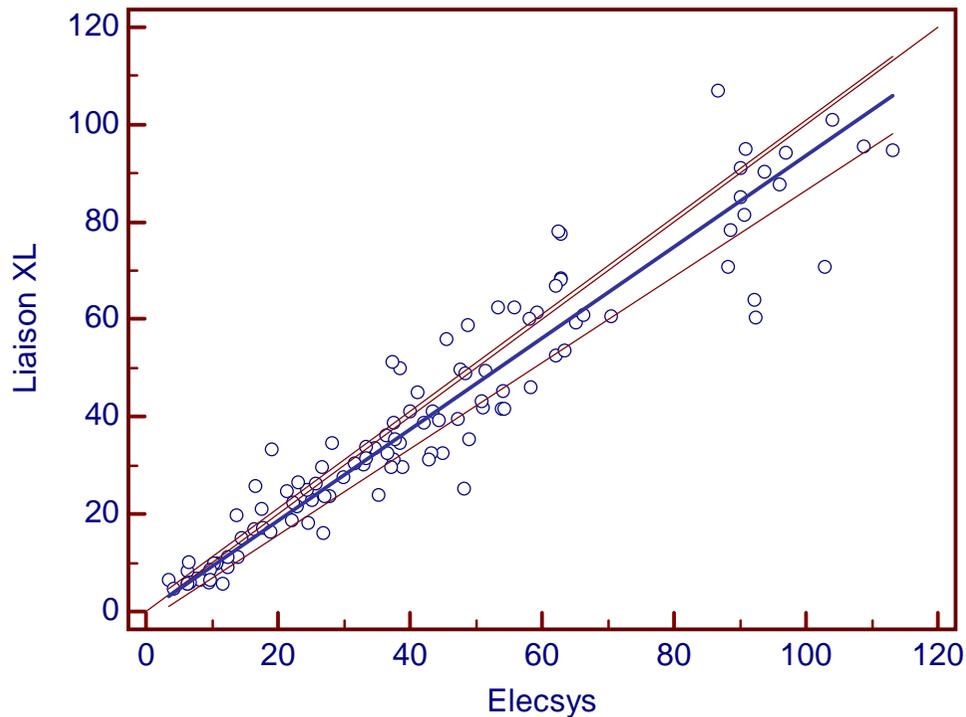
Intercept A	0,70
95% CI	-1,15 to 2,2
Proportional differences	
Slope B	0,91
95% CI	0,87 to 0,95

No significant systematic difference

Significant proportional difference

Roche Elecsys

Liaison XL = 0,94 x Elecsys - 0,16

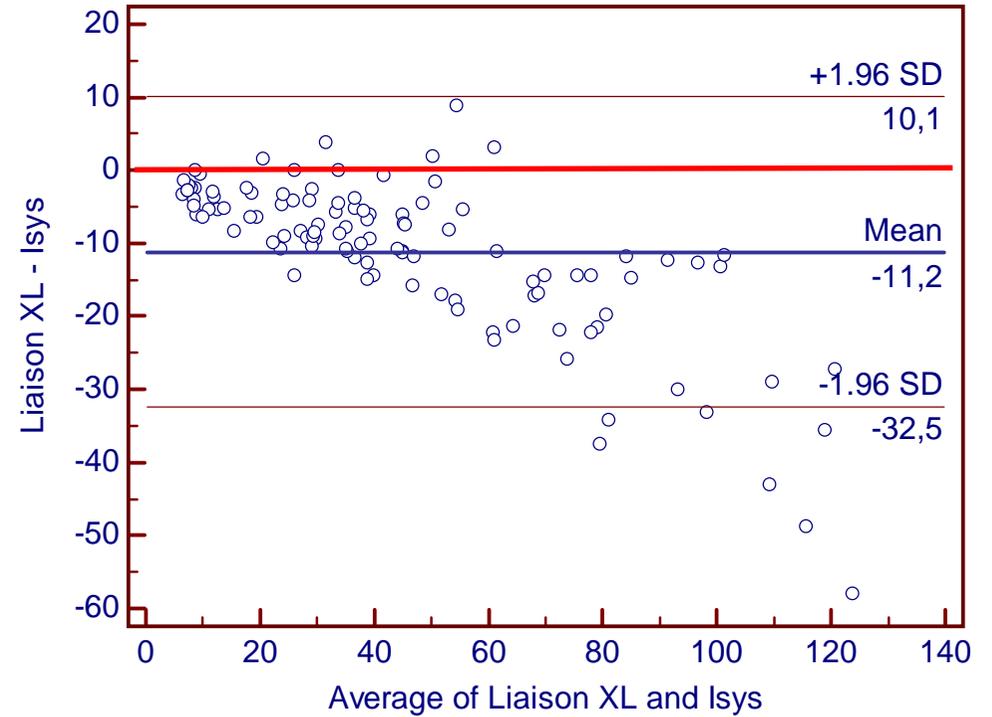
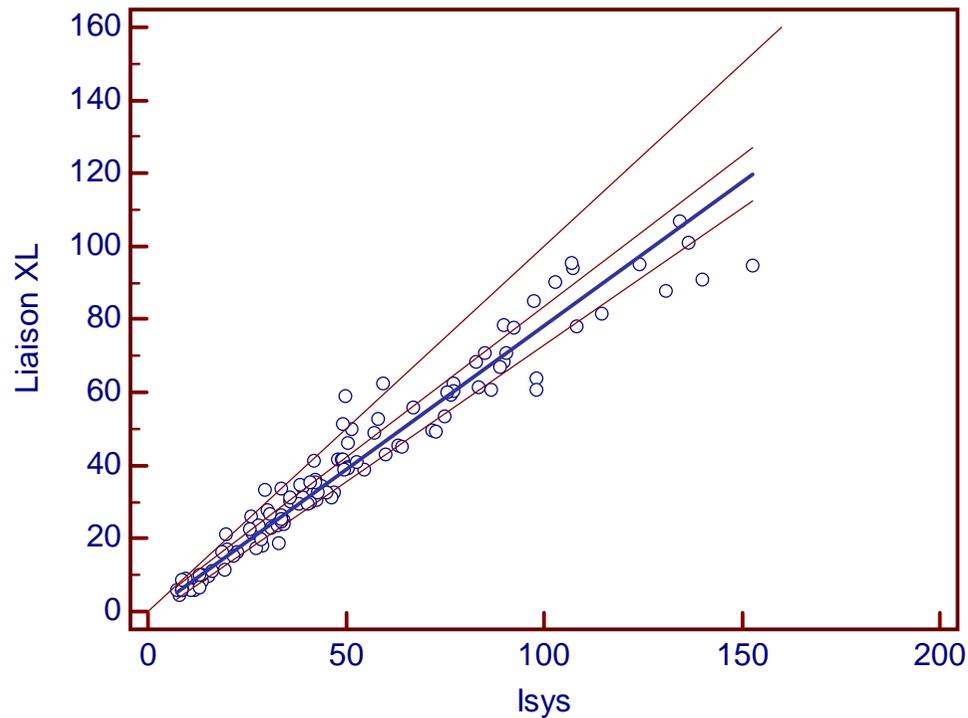


Intercept A	-0,16
95% CI	-1,89 to 1,28
Proportional differences	
Slope B	0,94
95% CI	0,89 to 1,00

No significant systematic difference
No significant proportional difference

IDS iSYS

$Liaison\ XL = 0,79 \times iSYS - 0,53$



Intercept A	-0,53
95% CI	-2,16 to 0,88
Proportional differences	
Slope B	0,79
95% CI	0,75 to 0,83

No significant systematic difference

Significant proportional difference

Conclusions

- 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 (especially in the lower range)
- Comparison studies show the good agreement with the DiaSorin RIA, Roche Elecsys and Siemens Centaur. LCMS-MS assays and iDS iSYS are calibrated differently.