

Evaluation of the new Dxl 9000 ACCESS HBsAg assay

P0076

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AIM

Hepatitis B surface antigen (HBsAg) is the most important screening marker for active Hepatitis B infections. Laboratory based high throughput assays are not only required for identifying persons with an ongoing infection and treatment monitoring, but also for screening blood donors. We compare the performance of the new Beckman Coulter Dxl 9000 ACCESS HBsAg (Dxl 9000) against the Abbott Alinity i HBsAg Next Qualitative Reagent Kit (Alinity i) and the Beckman Coulter Dxl 800 ACCESS HBsAg (Dxl 800).

RESULTS

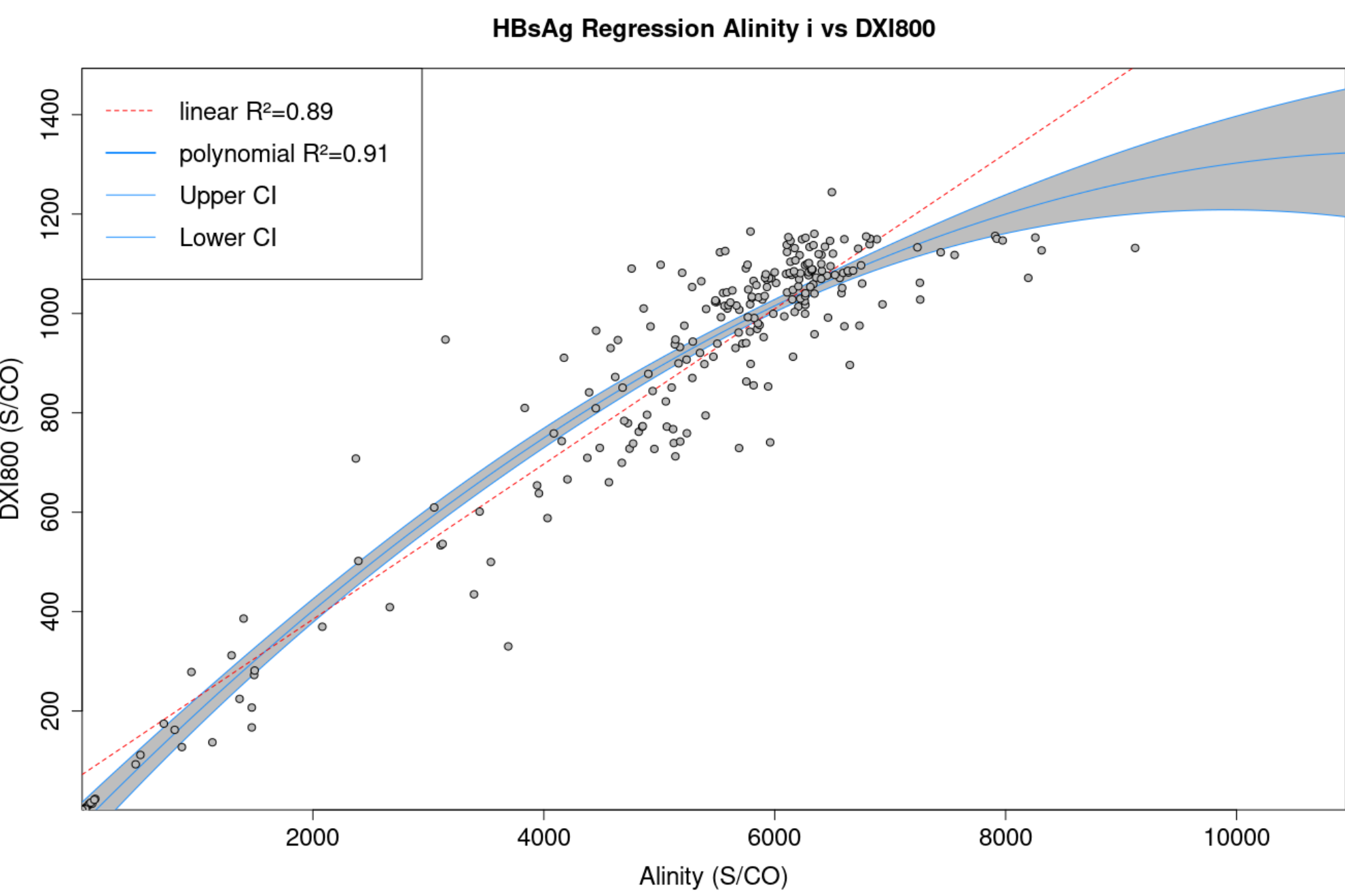
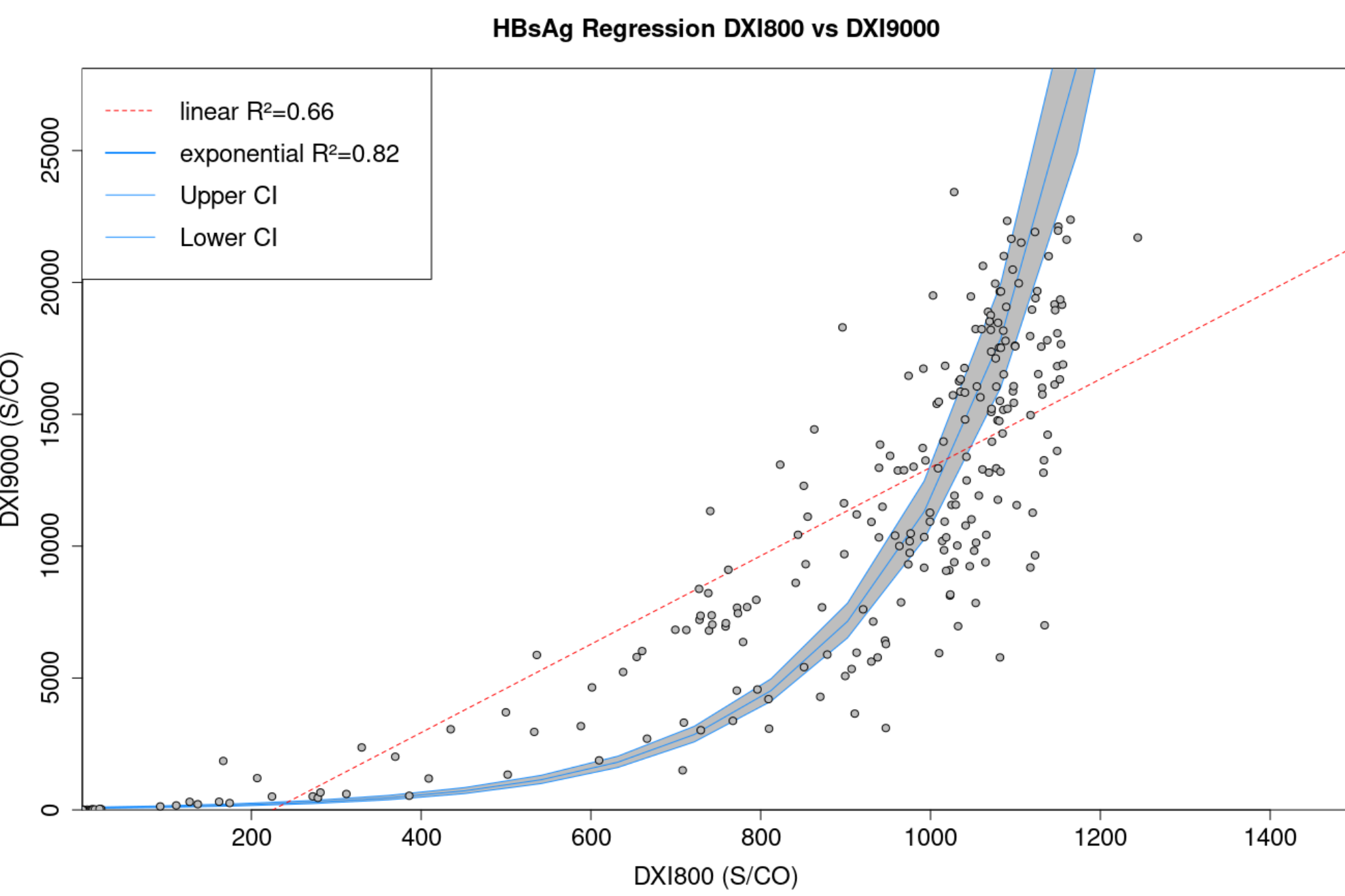
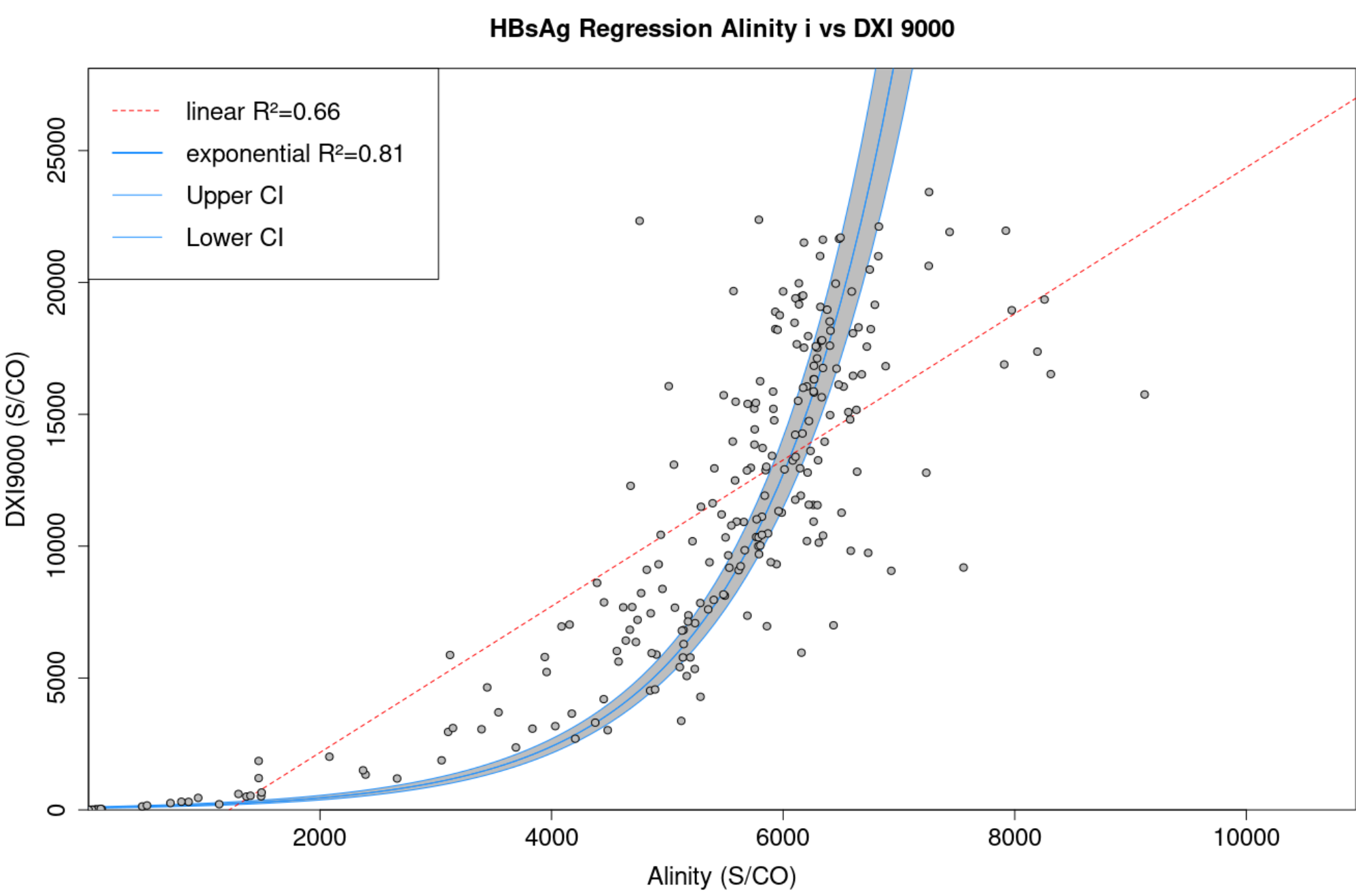
The agreement between the Dxl 9000, Dxl 800 and the Alinity i assay was >99%. Calculated sensitivity of Dxl 9000 against Alinity i was 100. Both assays showed low coefficients of variation with a sample that has been tested 5-fold (AI: 0.6% BC: 2.6%). The coefficients of correlation between Dxl 9000 and Alinity i were 0.66 using a linear model and 0.81 using an exponential model, as linear dynamic range of the BC assay was significantly larger.

Table 1 – 3: Contingency tables comparing Alinity i, Dxl 9000 and Dxl 800

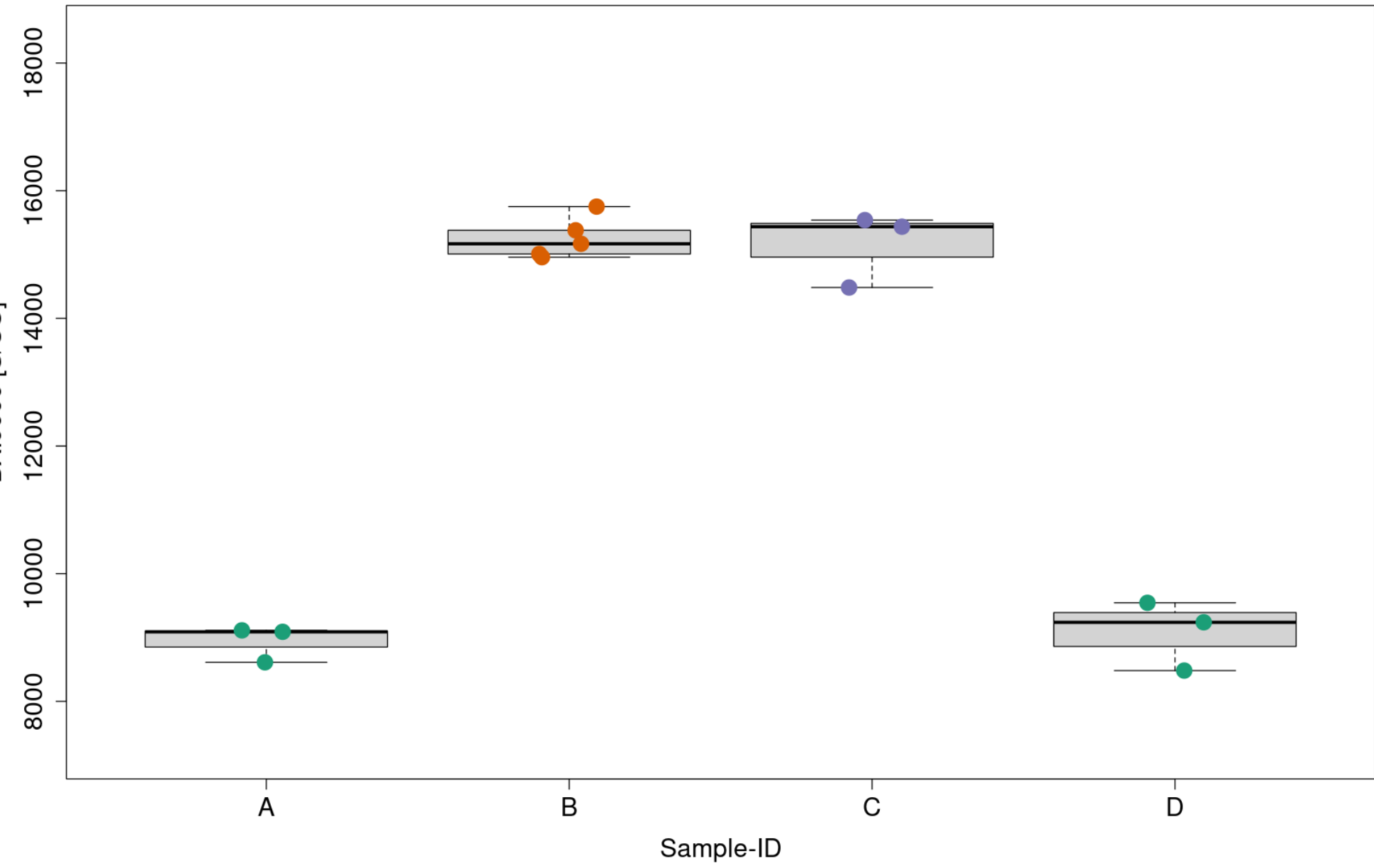
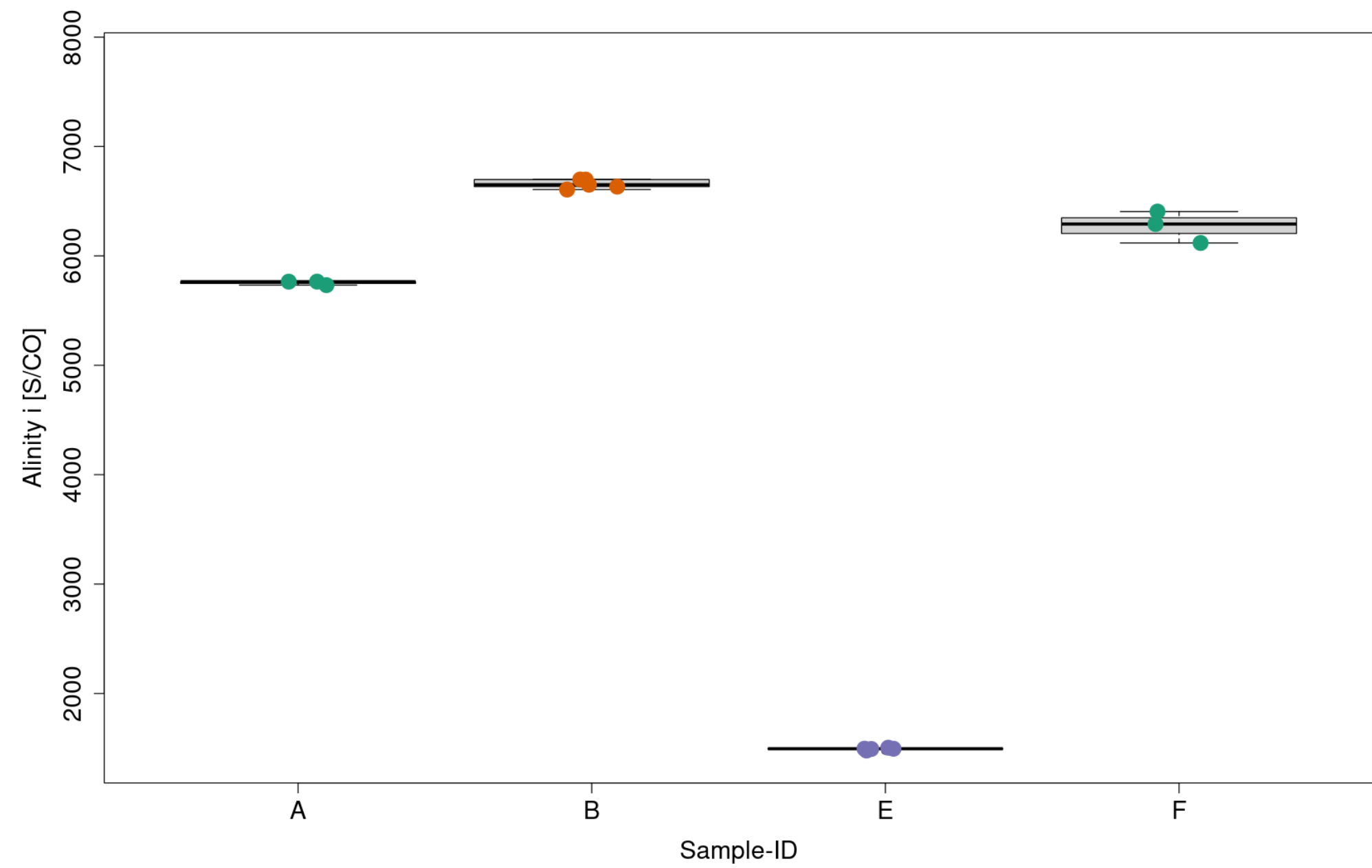
	Dxl 9000	
Alinity i	neg	pos
neg	133	1
pos	0	248
	382	
Sensitivity	100,0%	
Specificity	99,6%	
Agreement	99,7%	

	Dxl 9000	
Dxl 800	neg	pos
neg	132	0
pos	1	249
	382	
Sensitivity	99,6%	
Specificity	100,0%	
Agreement	99,7%	

	Dxl 800	
Alinity i	neg	pos
neg	132	2
pos	0	248
	382	
Sensitivity	100,0%	
Specificity	99,2%	
Agreement	99,5%	



Figures 1 – 3: Plots comparing 241 positive samples - Alinity i, Dxl 9000 and Dxl 800



Figures 4 – 5: Coefficient of correlation - Alinity i and Dxl 9000

METHODS

382 samples from routine diagnostic, pre-tested with the Dxl 800 Access HBs Ag (250 reactive, 132 non-reactive) were compared on both assays. Assay variation was investigated by repeat testing of a specific sample on BC and AI. Despite both assays are not calibrated against the WHO international standard, the signal to cutoff (S/CO) where compared using regression analysis. Clinical samples where repeatedly tested on different days to assess assay variation. Statistical analysis and graphical representation was generated with R statistical package.

CONCLUSIONS

The new Dxl 9000 ACCESS HBsAg assay shows a very high agreement to the Alinity i HBsAg Next Qualitative Reagent Kit with excellent sensitivity and specificity. Besides the high degree of automation and throughput the large dynamic range the Dxl 9000 ACCESS HBsAg assay proves to be an excellent assay for the virology routine laboratory.