Evaluation of the new DxI 9000 ACCESS anti-HCV assay

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AIM

Detection of antibodies against Hepatitis C Virus is still the most frequent method of screening for Hepatitis C infections. Laboratory based high throughput assays are not only required for identifying persons with a previous infection, but also for screening blood donors. We compare the performance of the new Beckman Coulter DxI 9000 ACCESS anti-HCV (BC) against the Abbott Alinity i Anti-HCV Reagent Kit (AI).

METHODS

312 samples from routine diagnostic, pre-tested with the DxI 800 Access HCV Ab V3 (116 reactive, 196 non-reactive) were compared on both assays. Assay variation was investigated by repeated testing of specific samples near the cut-off on DxI 9000 and Alinity i. Despite both assays are not calibrated against the international standard, the signal to cutoff (S/CO) where compared using regression analysis.

RESULTS

The agreement between the DxI 9000 and the Alinity i assay was 97.8%, with high sensitivity and specificity (s. Tab.1). Five samples showed reactive results in the Alinity i and negative in the DxI 9000. Three of those samples showed no reactivity in an immunological confirmation assay or NAT and two sample were of patients with a resolved hepatitis C. Two samples showed negative results in the Alinity i and reactive in the DxI 9000. Both samples showed no reactivity in NAT or serological confirmation assay. In the normalization across the HCV genotypes, the comparison between DxI 9000 and Alinity I (Fig. 2) shows no failure for one of the tested genotypes. Both assays showed low coefficients of variation with samples near the cut-off that has been tested 5-fold (AI: 4.7% BC: 7.2%; s. Fig. 3).

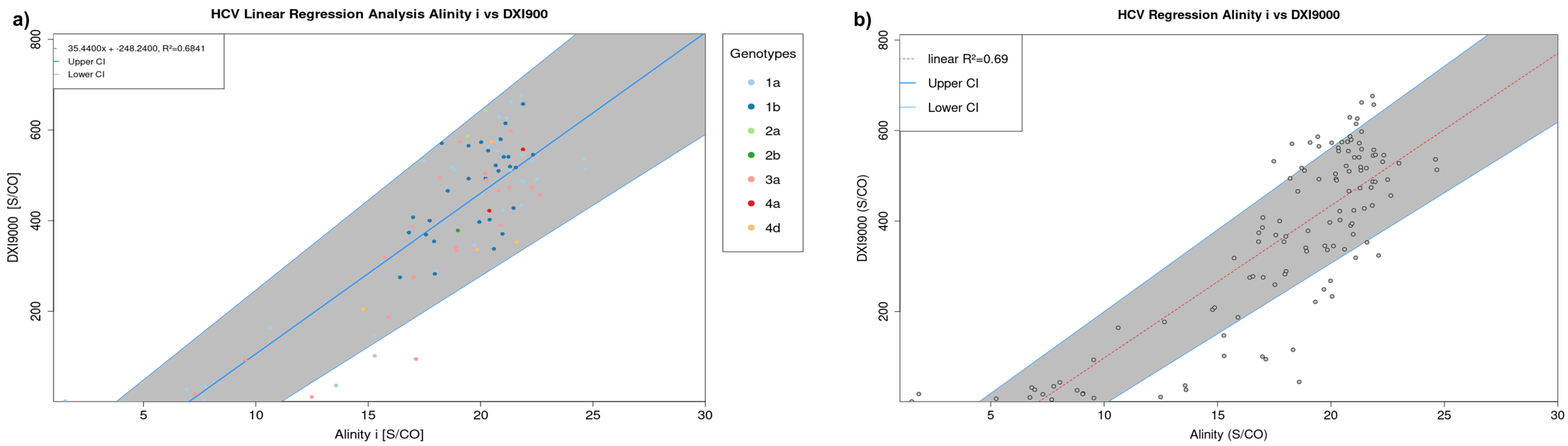

Fig. 1 a-b: Regression analyses for HCV (a) and for all tested samples (b).

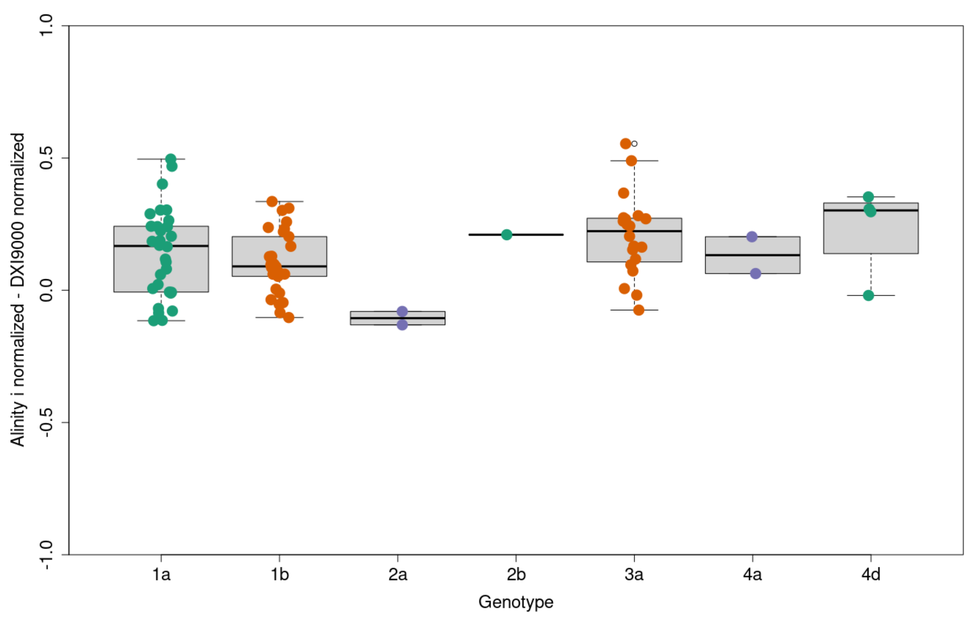

Fig. 2: Comparison of normalized detection sorted by HCV genotypes

Tab. 1: Total agreement with the Alinity i, sensitivity and specificity for the DxI 9000

	DxI 9000	
Alinity i	**neg**	**pos**
neg	198	2
pos	5	107
		312
Sensitivity	95,5%	
Specificity	98,2%	
Agreement	97,8%	

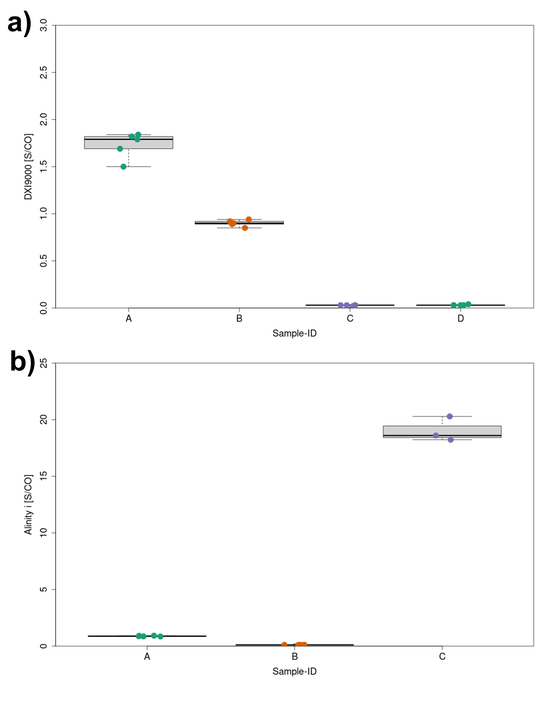

Fig. 3: Coefficient of variation near cut-off point in HCV positive and negative samples in 5fold measurements for a) DxI 9000 and b) Alinity i

CONCLUSIONS

The new DxI 9000 ACCESS anti-HCV shows a high agreement to the Alinity i Anti-HCV Reagent Kit with good sensitivity and specificity. In addition to the high degree of automation and the fast throughput, the large dynamic range of the ACCESS anti-HCV assay proves to be an excellent diagnostic test for the routine virology laboratory.