Evaluation of the new DxI 9000 Anti-HIV Antibody and Antigen Combo assay

P0025

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AIM

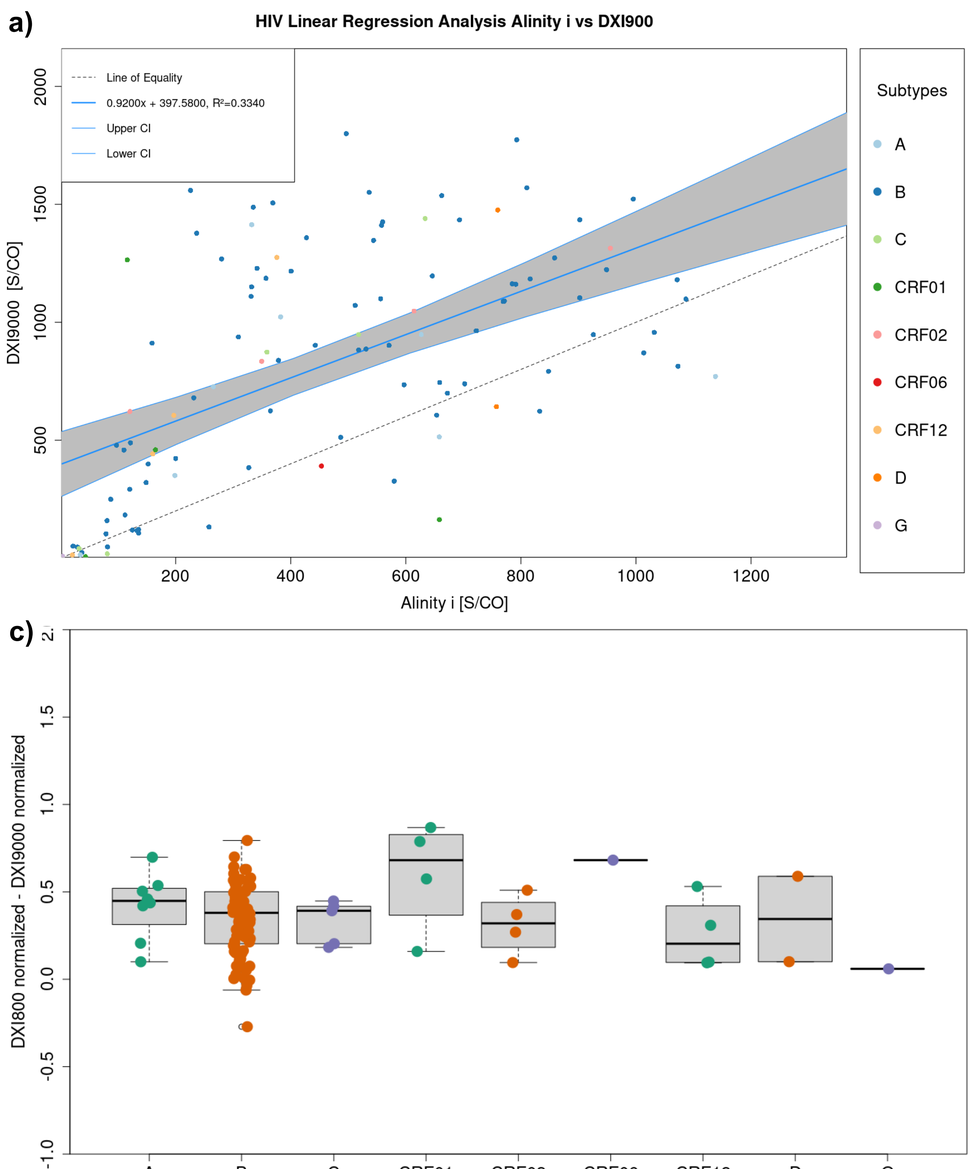
The foundation of HIV diagnostics are immunological screening assays. Those assays are nowadays combining detection of antibodies against HIV protein and detection of p24 Antigen. Most tests are performed as laboratory based high-throughput assays as they show the highest sensitivity and specificity. Therefore, they can be used for multiple applications like screening blood donors or checking for infections in case of risk contacts. We compare the performance of the new Beckman Coulter DxI 9000 ACCESS HIV Ag/Ab combo (BC) against the Abbott Alinity i HIV Ag/Ab Combo Reagent Kit (AI).

METHODS

437 samples from routine diagnostic, pre-tested with the DxI 800 Access HIV combo V2 Assay (211 reactive, 226 non-reactive) were compared on both assays. 8 samples were identified as having a false positive reaction with the DxI 800 Access HIV combo V2, having a negative serological confirmation assay and undetectable viral load, before they were retested with both assays, BC and AI. Assay variation was investigated by repeat testing of a specific sample on BC and AI.

RESULTS

The signal-to-cut-off values of the two tests, AI and BC, did not show a clear correlation in the regression analyses, neither with a linear nor with a polynomial function. This applies to the HIV-1 subtypes (Fig.1a) as well as to the overall measurements (Fig.1b). The systems are obviously configured differently here. However, the agreement in the qualitative analysis between the tests is excellent at over 99% (s. Tab.1). In the normalization across the HIV-1 subtypes, neither the comparison between DxI900 and BC (Fig.1c), nor between BC and AI (Fig.1d) shows a failure for one of the tested subtypes.
The 8 false (DxI 800) positive samples showed non-reactive results with the BC and AI assay and were correctly classified. Both assays showed low coefficients of variation with a sample that has been tested 5-fold (AI: 1.5% BC: 0.5%). In the Regression analysis



Tab. 1: Total agreement with the AI, sensitivity and specificity for the BC

	Dxl 9000	
Alinity i	**neg**	**pos**
neg	231	1
pos	2	203
		437
Sensitivity	99,0%	
Specificity	99,5%	
Agreement	99,3%	

Fig. 1 a-d: Regression analyses for HIV-1 non B-subtypes in a linear model (a) and for all tested samples, linear and polynomial model (b). Figures c) and d) show normalized analyses for the different tested subtyps for DxI800 / CxI9000 and Alinity I / DxI9000 respectively.

CONCLUSIONS

The new ACCESS HIV Ag/Ab combo for the DxI 9000 shows a high agreement to the Alinity i HIV Ag/Ab Combo Reagent Kit with good sensitivity and specificity for all tested HIV-1 subtypes. The high degree of automation and high throughput are a very good support for the virology routine laboratory.