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Performance of 9 rapid diagnostic HIV tests on a wide panel of whole blood samples

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BACKGROUND

Rapid diagnostic HIV tests (RDTs) are now used in and outside laboratories or as self-tests, to improve HIV diagnosis coverage. RDTs performances are classically tested on serum, and more rarely on whole blood, limiting interpretation on a "real life" use. Moreover, most of the RDTs tested only detect antibodies (3rd generation). We tested the performance of 9 RDTs, including two detecting p24 and antibodies (4th generation) on a large panel of fresh and reconstituted whole blood samples, corresponding to diverse clinical status and representative of the wide genetic diversity of HIV.

METHOD

Seven 3rd generation RDTs and two 4th generation RDTs were tested (Table 1). The specificity of the tests was evaluated on 200 negative samples collected from patients in our sexually transmitted disease clinic. The sensitivity was evaluated on 300 positive samples referenced in our National Reference Center (NRC) collections. These latter were representative of HIV diversity, including HIV-1/O and HIV-2; and 50 were collected during the primary HIV infection (PHI) phase. We validated a method of whole blood reconstitution that corresponded to a mix of selected serum (frozen collection) with fresh cells (separated from fresh whole blood), to mimic whole blood.

3rd generation RDTs	
STAT-VIEW HIV 1/2 *	Chembio diagnostic systems
EXACTO PRO TEST HIV	Biosynex
EZ-TRUST HIV 1 & 2 Rapid Screen Test	CS Innovation Ltd [£]
Genie Fast HIV1/2	Bio-Rad
HIVTOP	Biosynex
INSTI **	bioLytical
VIKIA HIV 1/2	bioMérieux
4th generation RDTs (Ag+Ab)	
BioTechMed HIV1/2 Rapid-4	BioTechMed [£]
HIV Combo	Alere

Distributed in France by *AAZ; **Nephrotek

[£] supplied by a provider on the internet

Table 1 : List of the different RDTs tested

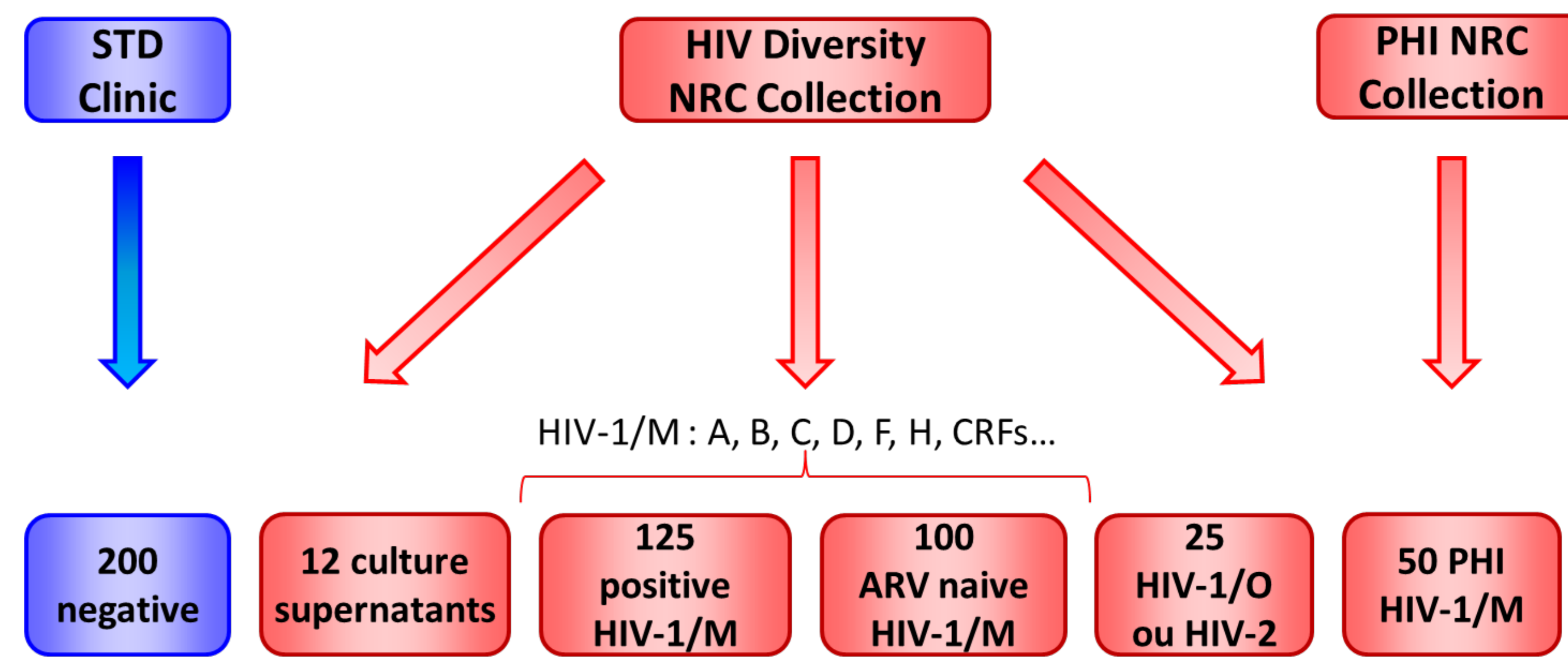


Figure 1 : Composition of the sample panel

RESULTS

SPECIFICITY

Negative samples N=200	Stat View	HIV Combo		EZ Trust	EXACTO	Genie Fast	HIVTOP		Vikia	INSTI	HIV ½ Rapid 4 ³	
		Ag	Ac				T1	T2			T1	T2
		Specificity										
	0	1	0	0	3	0	2	0	1	0	0	0
	100%	99,50%	100%	100%	98,50%	100%	99%	100%	99,50%	100%	100%	100%

*: n=30 samples T1 = test HIV-1 T2 = test HIV-2

SENSITIVITY WITH HIV-1/M SAMPLES

HIV-1/M samples N=225 [£]	Stat View	HIV Combo		EZ Trust	EXACTO	Genie Fast	HIVTOP		Vikia	INSTI	HIV ½ Rapid 4 ³	
		Ag	Ac				T1	T2			T1	T2
		Sensitivity										
	225	6	225	225	225	225	225	116	225	225	60	0
	100%	NA	100%	100%	100%	100%	100%	NA	100%	100%	100%	NA

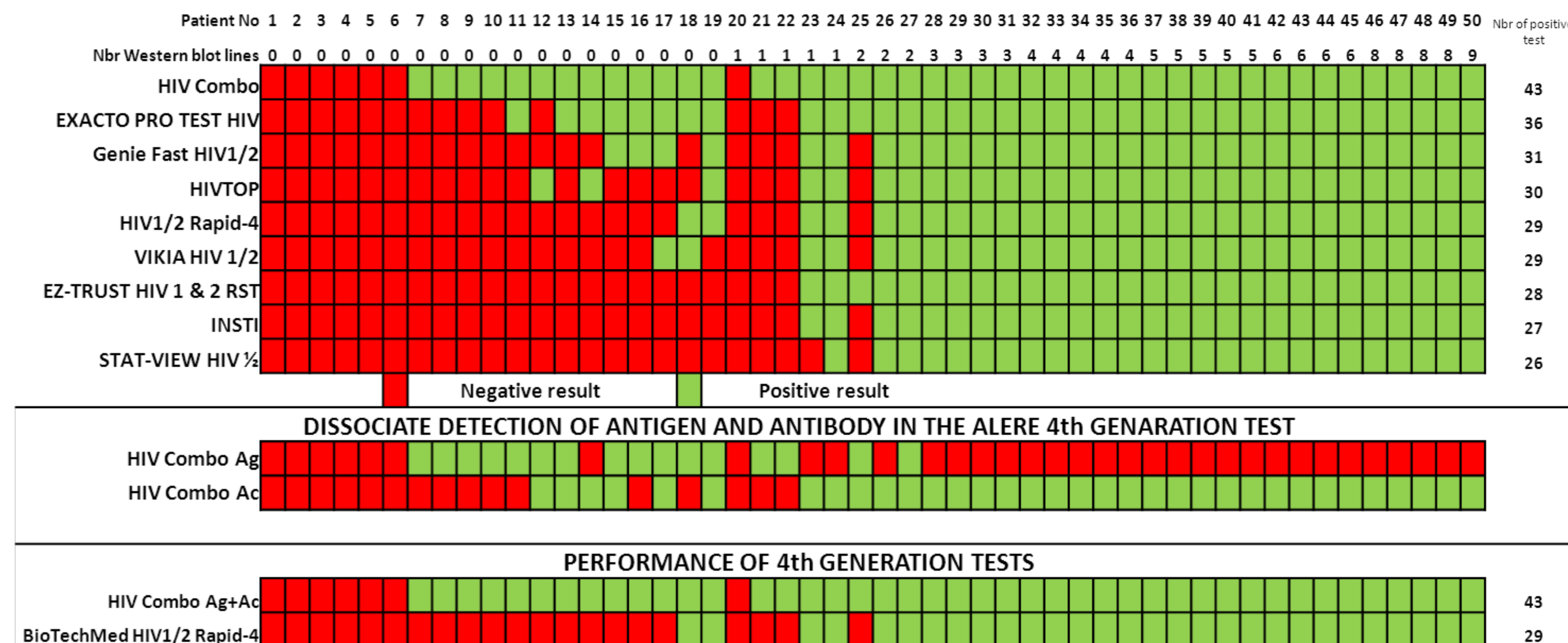
*: n=60 samples; [£]: of which 100 were collected from ARV naive patients T1 = test HIV-1 T2 = test HIV-2

SENSITIVITY WITH HIGHLY DIVERGENT HIV

HIV-1/O	Stat View	HIV Combo		EZ Trust	EXACTO	Genie Fast	HIVTOP		Vikia	INSTI	HIV ½ Rapid 4	
		Ag	Ac				T1	T2			T1	T2
		Sensitivity										
N=10	9	0	10	6	8 (7)	6 (4)	8 (7)	0	10	6	2 (1)	0
	90%	NA	100%	60%	80%	60%	80%	NA	100%	60%	20%	NA
HIV-2	Stat View	HIV Combo		EZ Trust	EXACTO	Genie Fast	HIVTOP		Vikia	INSTI	HIV ½ Rapid 4	
		Ag	Ac				T1	T2			T1	T2
		Sensitivity										
N=13	13	0	13	13	13	13 (12)	4	13	13	13	1	7
	100%	NA	100%	100%	100%	100%	NA	100%	100%	100%	NA	54%
HIV-1+2	Stat View	HIV Combo		EZ Trust	EXACTO	Genie Fast	HIVTOP		Vikia	INSTI	HIV ½ Rapid 4	
		Ag	Ac				T1	T2			T1	T2
		Sensitivity										
N=2	2	0	2	2	2	2	2	2	2	2	2	1
	100%	NA	100%	100%	100%	100%	100%	100%	100%	100%	100%	50%

(): Number of positive samples after the early reading time recommended by the manufacturer T1 = test HIV-1 T2 = test HIV-2

PERFORMANCE DURING THE PHI



CONCLUSION

Our method of reconstituted whole blood allowed us to evaluate RDTs close to real-life conditions, on a large panel of samples in terms of genetic diversity and clinical status. No difference was observed for diagnosis of HIV-1/M infections; nonetheless, divergent HIV-1/O samples remains of concern, with only 2 tests detecting them all. Use of 4th generation RDT can significantly increase the diagnosis of primary infection, but results are largely depending on the test used, the HIV BioTechMed Rapid-4 being worse than some 3rd generation RDTs.