EVALUATION OF A NEW RAPID TEST: VIKIA® HIV 1/2

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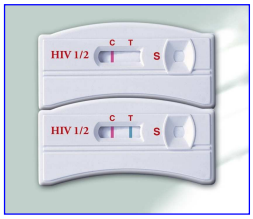
INTRODUCTION

Simple tests are needed for large-scale, decentralized diagnosis of HIV infection, particularly in resource-limited regions. The VIKIA® HIV 1/2 device (bioMérieux) is a new simple and rapid test for the detection of anti HIV-1 and HIV-2 antibodies in human sera, plasma or whole blood (venous or capillary).
Rapid tests need to be adapted to the genetic diversity circulating in the world and present high analytical performances of sensitivity and specificity. For this purpose, new rapid test should be evaluated on large panels of samples representative of the epidemiological situation, not only representative of the situation in industrialized countries.
The aim of this work was to evaluate the performance of VIKIA HIV 1/2 in a multi-center collaborative study in Europe associated to West Africa.

MATERIAL AND METHODS



Principle:

VIKIA HIV 1/2 is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2.

The plastic device contains:

1. A chromatography membrane to which are fixed:
- in the test region ("T"), synthetic peptides specific for HIV-1(gp41 of group M and group O), and HIV-2 (gp36),
- in the control region, two color indicators.

2. A test strip impregnated with a conjugate consisting of a mixture of synthetic peptides specific for HIV-1 group M (gp41 of group M and group O), and HIV-2 (gp36), coupled to blue-dyed polystyrene microspheres (serum, plasma, venous or capillary blood).

The sample (75µL) is added to the sample well and migrates by capillarity along the membrane. Reading is done at 30 minutes.
If the sample contains anti-HIV antibodies they form an antigen-antibody complex with the peptides, specific to this virus, present on the blue-dyed polystyrene microspheres. This is revealed by a blue line in the test region "T". The test is validated if the color of the control line in region "C" changes from blue to red.

Specificity study:

Specificity was evaluated on plasma and venous whole blood from 2228 subjects.
- 1287 blood donors (from Burkina-Faso 23% and France 77%),
- 202 hospitalized patients (France),
- 267 pregnant women (Burkina-Faso 18% and France 82%),
- 344 patients with high risks (Burkina-Faso 73% and France 27%),
- 128 serum/plasma and reconstituted whole blood (to mimic fresh whole blood not available) of interfering samples (France).

Sensitivity study:

Sensitivity was evaluated on plasma and venous whole blood from :
- 479 HIV-1 and HIV-1+2 seropositive patients (Burkina-Faso / Ivory Cost, 55% and France 45%),
- 247 serum/plasma and reconstituted whole blood or fresh whole blood of HIV-2 seropositive patients (Ivory Cost 59% and Portugal 41%),
- 41 serum/plasma and reconstituted whole blood of patients infected by HIV-1 group M (N=30, 3A, 3B, 3C, 3D, 3F, 4G, 3H, 2CRF01, 5CRF02 and 1CRF11) and 11 HIV-1 group O (France) = HIV diversity panel,
- Serum/plasma and reconstituted whole blood from 29 commercial seroconversion panels (Zeptometrix and BBI) and the SFTS panel (France).

We also compared the performances of the 3 types of samples: fresh plasma, venous whole blood and capillary whole blood, on 146 paired samples, including 46 with a negative status and 100 with a positive status.

RESULTS

Specificity study:

Blood donor population: n = 1287

Population	Number of tested samples with HIV-negative status	Samples type	Negative by VIKAI HIV 1/2 Reading at 30 minutes
Europe	1000	Plasma	997 Specificity: 99.70% with 95%CI [99.10 - 99.90]
		Venous whole blood	999 Specificity: 99.90% with 95%CI [99.42 - 99.98]
West Africa	287	Plasma	287 Specificity: 100% with 95%CI [98.63 - 100]
		Venous whole blood	287 Specificity: 100% with 95%CI [98.63 - 100]

Specificity for VIKIA HIV ½ for the overall population:
Plasma : 99.77% 95%CI [99.30 - 99.92]
Whole Blood : 99.92 % 95%CI [99.55 - 99.99]

Hospitalized patients: n = 202

Population	Number of tested samples with HIV-negative status	Samples type	Negative by VIKAI HIV 1/2 Reading at 30 minutes
Europe	202	Plasma	201 Specificity: 99.50% with 95%CI [97.17 - 99.92]
		Venous whole blood	202 Specificity: 100% with 95%CI [98.06 - 100]

Pregnant women: n = 267

Population	Number of tested samples with HIV-negative status	Samples type	Negative by VIKAI HIV 1/2 Reading at 30 minutes
Europe	219	Plasma	217 Specificity: 99.09% with 95%CI [96.66 - 99.75]
		Venous whole blood	219 Specificity: 100% with 95%CI [98.21 - 100]
West Africa	48	Plasma	48 Specificity: 100% with 95%CI [92.31 - 100]
		Venous whole blood	48 Specificity: 100% with 95%CI [92.31 - 100]

Specificity for VIKIA HIV ½ for the overall population:
Plasma : 99.25% 95%CI [97.25 - 99.80]
Whole Blood : 100 % 95%CI [98.52 - 100]

High-risk patients: n = 344

Population	Number of tested samples with HIV-negative status	Samples type	Negative by VIKAI HIV 1/2 Reading at 30 minutes
Europe	94	Plasma	94 Specificity: 100% with 95%CI [95.92 - 100]
		Venous whole blood	94 Specificity: 100% with 95%CI [95.92 - 100]
West Africa	250	Plasma	250 Specificity: 100% with 95%CI [98.43 - 100]
		Venous whole blood	250 Specificity: 100% with 95%CI [98.43 - 100]

Specificity for VIKIA HIV ½ for the overall population:
Plasma : 100% 95%CI [98.85 - 100]
Whole Blood : 100 % 95%CI [98.85 - 100]

The global specificity was 99.6% for plasma and 99.9% for whole blood.
No cross-reactivity was found among the interfering samples.

Sensitivity study:

HIV-1 and HIV-1+2 positive samples: n = 479

Population	Number of tested samples with HIV-negative status	Samples type	Negative by VIKAI HIV 1/2 Reading at 30 minutes
Europe	218	Plasma	218 Sensitivity: 100% with 95%CI [98.20 - 100]
		Venous whole blood	218 Sensitivity:100% with 95%CI [98.20 - 100]
West Africa	261	Plasma	260 Sensitivity: 99.62 % with 95%CI [97.80 - 99.93]
		Venous whole blood	260 Sensitivity: 99.62 % with 95%CI [97.80 - 99.93]
Total	479	Plasma	478 Sensitivity: 100% with 95%CI [98.79 - 99.96]
		Venous whole blood	478 Sensitivity: 100% with 95%CI [98.79 - 99.96]

One blood donor sample was positive result by ELISA with a value approaching the cut-off, and was found to be negative by the VIKIA HIV ½ test and another rapid test marketed in Europe. For this sample, the Western-blot HIV-1 was positive but showed lines with weak colour intensity, and the P24 Ag was negative (the viral load could not be tested for this sample).

HIV-2 positive samples: n = 247

Population	Number of tested samples with HIV-negative status	Samples type	Negative by VIKAI HIV 1/2 Reading at 30 minutes
Europe	102	Plasma	101* Sensitivity: 99.02% with 95%CI [94.51 - 99.83]
		Venous whole blood	102 Sensitivity:100% with 95%CI [96.23 - 100]
West Africa	145	Plasma	144* Sensitivity: 99.31 % with 95%CI [96.09 - 99.88]
		Venous whole blood	145 Sensitivity: 100 % with 95%CI [97.32 - 100]
Total	247	Plasma	245 Sensitivity: 99.19% with 95%CI [97.03 - 99.78]
		Venous whole blood	247 Sensitivity: 100% with 95%CI [98.41 - 100]

* 2 false negative serum or plasma samples associated with a Hook effect. This phenomenon was not observed for the same 2 samples when the test was performed with whole blood.

The global sensitivity was 99.6% for plasma and 99.9% for whole blood.
All the samples (serum/plasma and reconstituted whole blood) from the HIV diversity panel were found to be positive, except one group O sample which was found to be negative for plasma but positive for whole blood, and then systematically positive after retesting for both type of samples.
The comparison between the 3 types of samples (fresh plasma, venous whole blood and capillary whole blood) showed perfect concordance.

Seroconversion panels:

		VIKIA being positive as early as with the most sensitive ELISA (3rd and 4th generation)		VIKIA being positive as early as with the half of ELISA tested (3rd and 4th generation)	
	Total number of panels	Number	%	Number	%
Serum	29	19	65.5%	27	93.10%
Reconstituted whole blood	29	15	51.72%	24	82.76%

CONCLUSION

The VIKIA HIV 1/2 test presents high performance in terms of specificity and sensitivity. These performances were higher with venous whole blood, allowing its use with this type of sample as well as with capillary whole blood.
The results of the seroconversion panels show that detection with the VIKIA HIV 1/2 test is less sensitive with whole blood samples than with plasma samples, but that it is obtained as early as with most ELISA tests (3rd and 4th generation).
This evaluation performed in Europe and in West Africa demonstrates the application in field conditions, and the excellent performances for samples from West-African populations.
Its simplicity and its use on venous or capillary blood make this tool very useful in resource-limited settings as well as more industrialized countries.

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