Development of a new HIV Immunochromatographic assay for the rapid detection of Human Immunodeficiency Virus antibodies

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INTRODUCTION

VIKIA® HIV 1/2 is a new rapid test using immuno-chromatography technology (ICT or lateral flow) (Figure 1). It was developed by bioMérieux for the qualitative detection of HIV antibodies in serum, plasma and whole blood.
This new test has been designed to detect human specific IgG and IgM: anti HIV-1 group M, anti HIV-1 group O and anti HIV-2.

OBJECTIVES

The objective of this study was to establish the performance characteristics of this new product in our R&D laboratory in comparison with 2 other kits commercialized in Europe : one rapid test (Determine HIV 1/2) and one ELISA microtiter -plate (Vironostika HIV Uniform II Plus O).

MATERIAL AND METHODS

The performance of the VIKIA HIV 1/2 assay was compared to the rapid test, Determine HIV 1/2 kit (Abbott, Japan) and the ELISA third generation test, Vironostika HIV Uniform II Plus O (bioMérieux, The Netherlands).

Details of the samples tested:
• 1090 negative clinical samples were tested in order to establish specificity:
- 1000 fresh blood bank samples
- 29 from Africa (from our collection)
- 71 potentially cross-reactive samples (from our laboratory's collection)

To establish sensitivity, we tested in parallel :
• 130 confirmed HIV positive samples from our collection
- 25 from Europe
- 78 from China
- 17 from Africa
- 5 HIV-1 group O
- 5 HIV-2
• 10 seroconversion panels from BBI and Zeptometrix

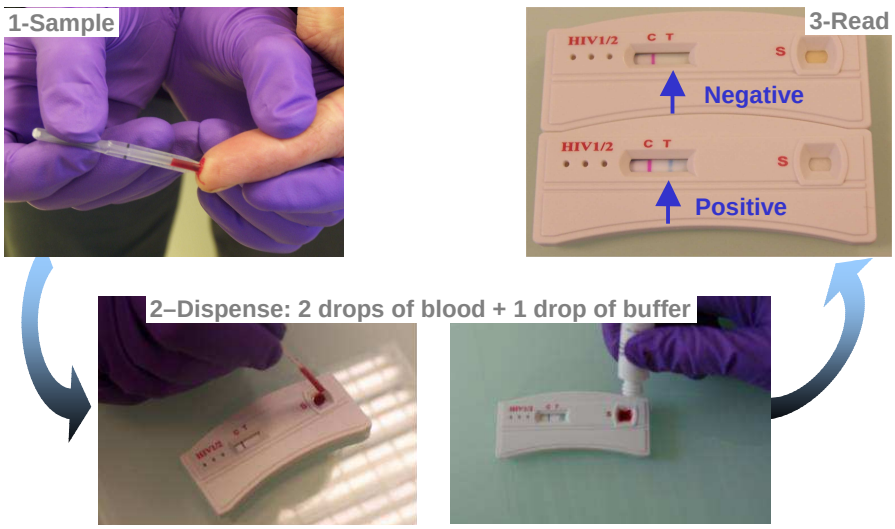

Fig.1: VIKIA HIV 1/2 (bioMérieux)

RESULTS

	Number samples tested	Abbott Determine	VIKIA HIV 1/2 pilot lot 1
Frozen Blood bank samples	500	98.6%	99.4%
Fresh Blood bank	500	99.2%	99.8%
Overall blood bank	1000	98.9%	99.6%
African samples	29	100%	100%
Potentially cross reacting including pregnant women	71	98,59%	98.59%
Total	**1090**	**98.8%**	**99.54%**

Fig.2: Specificity results

Specificity results:
The overall relative specificity (Figure 2) compared to Vironostika was 99.54% (95% CI = 98.91% - 99.81%) for VIKIA HIV 1/2 and 98.80% (95% CI = 97.94% - 99.30%) for Determine HIV-1/2.

Sensitivity results:
The relative sensitivity was 100% (95% CI = 97.01% - 100%) for both the VIKIA HIV 1/2 and Determine HIV 1/2 assays.

Seroconversion panels:
The same results were obtained with VIKIA HIV 1/2 and Determine HIV 1/2 on 8 panels. However, higher sensitivity was obtained with VIKIA HIV 1/2 on 2 panels.

Result discussion :
The results obtained during this preliminary study show that this new test has a performance equivalent to other HIV diagnostic tests available on the European market.
Further studies will be conducted on sera, plasma and whole Blood from HIV negative and positive patient to demonstrate performance equivalency.

CONCLUSION

This new assay shows a high level of sensitivity and specificity. The kit's early detection was demonstrated on the seroconversion panels. The combination of ease-of-use and high performance makes this product an excellent test for point-of-care patient testing.