



Evaluation of the Avioq VioOne HIV Profile Supplemental Assay as an alternative to the Bio-Rad Geenius HIV 1/2 Supplemental Assay



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Background

The recommended algorithm for HIV diagnosis distributed by the Centers for Disease Control and Prevention (CDC) (CDC 2018) states that clinical laboratories should perform a screening immunoassay for the detection of HIV-1/2 antibodies, an antibody differentiation assay, and potentially a nucleic acid test (NAT) for the confirmation of acute HIV infection.

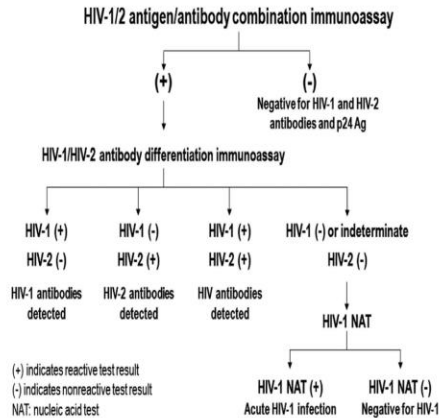
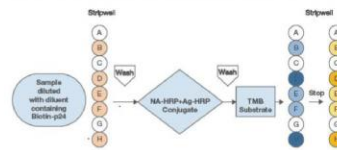


Figure 1. The CDC recommended algorithm for laboratory diagnosis of HIV infection.

Methods

In this study, 130 clinical serum specimens previously tested using the Bio-Rad Geenius Supplemental Assay were retested using the Avioq VioOne HIV Profile Supplemental Assay. Results from both platforms were compared to examine the performance of the Avioq VioOne HIV Profile Supplemental Assay.

Assay Procedure for VioOne™ HIV Profile™



Examples of results..

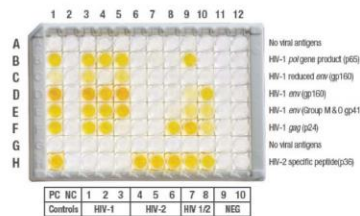


Figure 2. Overview of the VioOne HIV Profile assay procedure.



Figure 3. Bio-Rad Geenius Supplemental Assay cartridge.

Results

Results from the Bio-Rad Geenius HIV 1/2 Supplemental Assay and the Avioq VioOne HIV Profile Supplemental Assay passed accuracy criteria (>90%) with 99% concordance. There was only one discrepant result between the Geenius and the HIV Profile Assay.

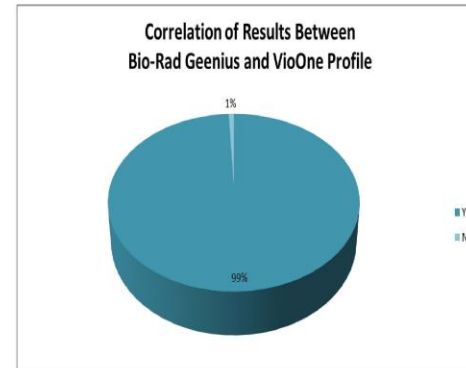


Figure 4. Correlation of results between both supplemental assays.

Conclusion

These studies comparing the Bio-Rad Geenius HIV 1/2 Supplemental Assay to the Avioq VioOne HIV Profile Supplemental Assay were satisfactory. Pending FDA approval, the Avioq VioOne Supplemental Assay is a suitable alternative testing method to the Bio-Rad Geenius Supplemental Assay for HIV differentiation and supplemental testing.

References:

Centers for Disease Control and Prevention, 2018. Quick reference guide: recommended laboratory HIV testing algorithm for serum or plasma specimens. *CDC Stacks. Updated January.*

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