

## **Evaluation of the Abbott Determine HIV-1/2 rapid assay using samples from the western cape region, South Africa.**

Sauer G, Brand T, Bester R, Beggs M, Arai H.X, Janse van Rensburg E.  
G. Sauer, Abbott Laboratories S.A., Diagnostic Division, PO Box 1616, Johannesburg 2000, South Africa  
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### Background

The Determine HIV -1/2 assay is a visually read, rapid immuno-chromatographic test for the qualitative detection of antibodies to HIV-1/2 in human serum, plasma, or whole blood. In this study the assay was evaluated by testing routine serum samples from Tygerberg Academic Hospital.

### Method

A total of 600 routine samples received at the serology section of the laboratory were tested with the normal laboratory procedure as well as the Determine assay. All samples were kept at 4°C and tested within two weeks of collection. The HIV protocol of the laboratory routinely screens all samples on the Abbott AxSym system and any positives are subsequently confirmed on a second ELISA (Vironostika HIV assay, Organon Teknika). The Determine assays' results were compared to that of the standard laboratory protocol. All tests were performed according to the manufacturer's protocols.

### Results

From the 600 samples tested 493 and 103 were true positives and true negatives respectively. The Determine assay yielded 4 incorrect results compared to the standard laboratory. 2 samples each gave false positive and false negative results. The sensitivity of the Determine assay was therefore calculated as 99.6% and the specificity as 98.0%.

### Conclusion

This rapid assay performed well compared to the laboratory's standard protocol and can be used as a screening test in epidemiological studies. Due to the fact that no cold-storage, special training, special equipment or reagents are required the assay is ideal to use under field conditions.