The accuracy of a rapid assay based testing algorithm using whole blood specimens; a field experience.

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Background

Today the diagnostic performance of many simple rapid (S/R) HIV assays is comparable to that of traditional ELISAs. Some of them can be performed with whole blood from finger-prick and require minimal equipment. These characteristics make them extremely useful in settings with limited facilities. Testing algorithms using S/R assays can be reliably used to quickly assess HIV serostatus.

The aim was to assess a serial S/R assay-based HIV testing algorithm using whole blood obtained by finger prick for the detection of HIV antibodies. The results were used in the multi-country HIV prevention trial of cellulose sulphate gel.

Objectives

To assess the sensitivity and specificity of an S/R assay-based serial testing algorithm, performed on EDTA blood obtained by finger prick, for the detection of HIV antibodies during a multi-centre HIV prevention trial.

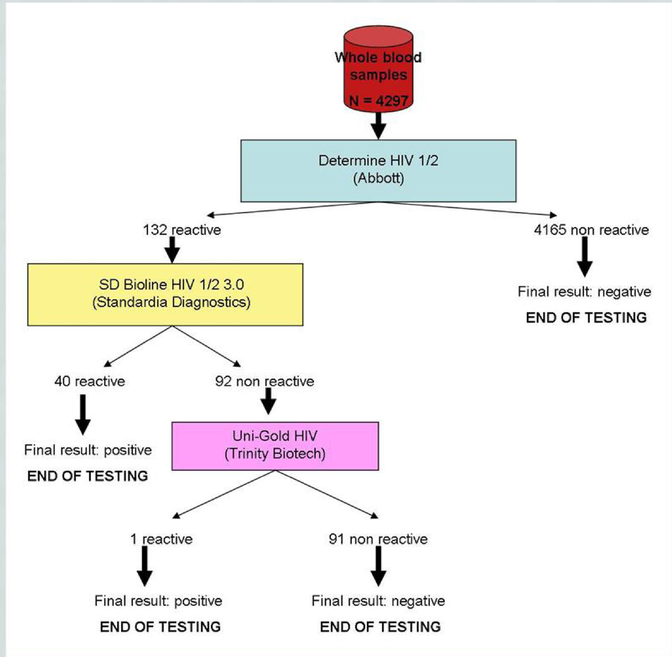
Study design

At all sites training was given on the performance and use of the S/R assays and the collection of whole blood by finger-prick. The quality of the different test batches was verified by the use of validation panels. An internal quality control panel was tested bimonthly during the trial.

HIV-negative participants were enrolled in the study and a minimum of 250µl finger-prick blood was collected in a microtainer containing EDTA as anti-coagulant at month 1, 3, 6 and 9. The specimens were tested in the S/R assay algorithm and a participant was only informed of her positive HIV status if the first positive algorithm was confirmed on a second whole blood specimen tested with the same algorithm. Plasma samples were obtained from all participants at their final visit and tested with qualitative HIV RNA-PCR, which was defined as gold standard.

Method

Specimens were tested in a serial procedure using three different rapid tests (Determine HIV 1/2 (Abbott), SD Bioline HIV 1/2 3.0 (STANDARD DIAGNOSTICS), Uni-Gold HIV (Trinity Biotech)). When there was a discordant result between the Determine and SD Bioline tests, the third assay (i.e. Uni-Gold) determined the final outcome.



Results

On a total of 4297 specimens tested, the algorithm showed a sensitivity of 100% (95% CL: 90.0%-100%) and a specificity of 99.9% (95% CL: 99.8%-100%). Two out of 4 initial false positives tested negative on a second whole blood specimen. The two other tested twice false positive on different whole blood specimens taken the same day and negative on a plasma sample collected later.

Majority of all false positive Determine results were seen at the beginning of the trial. Some test results were misinterpreted due to incomplete migration of the sample/antigen mixture. The exposure of the kit to too high room temperature and humidity could also be a reason for the less specific performance of the test.

Discussion and conclusions

This serial rapid test based HIV testing algorithm using whole blood obtained by finger prick is suitable for the identification of possible HIV infection in remote areas. Quality assurance measures should be implemented to guarantee good performance of the HIV rapid test using whole blood.