Abstract category: A57 Novel assays for virological monitoring

Title: A new point-of-care HIV-1 load monitoring assay for low resource settings: preliminary evaluation

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Background: Monitoring of antiretroviral therapy is difficult to implement in developing countries, particularly in Sub-Saharan Africa, due to the high cost of tests and lack of trained personnel. The Simple Amplification-Based Assay (SAMBA) Semi-quantitative HIV-1 Test has been developed as a robust, simple and rapid point-of-care (POC) nucleic acid platform to provide results within 1.5 hours. Its stability in high temperature and humidity circumvents the need for centralization of testing, cold chain, sample transport and storage. The simplicity of the test procedures does not require highly-trained personnel.

Methods: The SAMBA Semi-quantitative Test was developed to differentiate between patients with viral load (VL) above and below 1,000 cps/ml. Plasma samples were tested blinded by the SAMBA Semi-quantitative Test and results were compared to the COBAS® AmpliPrep/COBAS® TaqMan HIV-1 Test v2.0. Discrepant samples were resolved using the Abbott RealTime HIV-1 assay.

Results: When tested on 96 serial dilutions of subtype C samples, 134 UK clinical samples, 200 patient samples from Malawi and 154 patient samples from Uganda, the accuracy of the SAMBA HIV-1 Semi-quantitative Test was 97.2% (568/584, 95% CI 95.2-98.1) after accounting for the ±0.3 Log accuracy of commercial tests. The VL distribution of 70 untreated and 284 ART patient samples from Malawi and Uganda indicated that only 2.8% of samples were within the 1000± 0.3 log cut-off zone. In a population of 284 patients on ART for up to 10 years, 16.5% were identified as >1,000copies/ml by SAMBA (12.7% above and 1.4% within the cut-off zone and 2.5% misclassified) and checked for adherence or resistance to ART.

Conclusions: These data indicate that the SAMBA HIV-1 Semi-quantitative Test VL cut-off approach would be effective to identify virological failure in ART patients in a POC mode in sub-Saharan Africa. This approach is expected to decrease lost to follow-up limiting ART efficacy.

Country of research: Malawi, Uganda, United Kingdom