ABSTRACT

In developing countries with disproportionately high burden of HIV-1 (HIV) infections, access to early infant diagnosis (EID) and viral load (VL) HIV nucleic acid testing is limited by the prohibitive infrastructural costs of centralized testing laboratories. To increase access to HIVEID and VL monitoring, development of robust and low cost point of care (POC) technologies is a priority of current HIV diagnostic research. In Kenya, a number of POC technologies are being evaluated for EID and VL. One such POC technology is the simple amplification based assay (SAMBA) which is most advanced in its validation for use in a number of countries. However, in Western Kenya, with highest HIV prevalence, and possibly a wide range of HIV subtypes and recombinant forms, the performance of SAMBA has not been determined. The objective of the study was to evaluate the laboratory performance indices of SAMBA on HIV EID and VL testing. The study was cross sectional conducted in patient support facilities in 6 counties within Western Kenya region (namely Siaya, Nyamira, Kisii, Kisumu, Migori and Homabay counties). Male and female participants were recruited into the study and were distributed as follows: Infants aged <18 months (n=335) and adults aged >18 years (n=200). Patients were randomly recruited from the six counties. Whole blood from infants and plasma (separated at the facilities) from adults were collected from the facilities and shipped to the KEMRI/CDC Kisian testing laboratory. Whole blood were tested on SAMBA-qualitative (SAMBA-Q) assay for EID and plasma on SAMBA-semi-quantitative assay (SAMBA-SQ) for VL. All specimens were tested in parallel on the reference standard of care CobasAmpliprep/Taqman (CAP/CTM) assay. Specimens (n=11) with discordant results were further analyzed on Abbott m2000 as a tie breaker. In addition, total RNA was extracted from the discordant specimens, HIV *pol* gene amplified by RT-PCR and Nested PCR and genotyped by an in-house assay to determine the HIV subtypes. SAMBA-Q showed sensitivity, specificity and concordance of 100% (95% CI: 98.2-100), 99.3% (95% CI: 95.9-99.9) and Cohen Kappa of 0.99 (95% CI: 0.98-1.00) respectively. Similarly, SAMBA-SQ showed sensitivity, specificity and concordance of 92.0% (95% CI: 84.8, 96.5), 98.0% (95% CI: 93.0, 99.8) and Cohen Kappa of 0.90 (95% CI: 0.84- 0.96) respectively. The frequency of discrepancies between SAMBA and CAP/CTM was 2% (11/535).Among the 10successfully genotyped specimens 60% (n=6)were circulating recombinant forms (CRFs) AD(n=5)and AC(n=1) while 40% were pure subtype A1 (n=3)and A(n=1).SAMBA-Q and SAMBA-SQ had comparable accuracy and reliability to CAP/CTM in detecting and quantifying HIV hence should be considered for adoption as a POC to increase access to EID and VL testing in Western Kenya.