

Abstract

Background: The HIV Lateral Flow Tests (LFTs) provide a good compromise between accuracy, cost, speed and overall effectiveness. **Objective:** This study assessed the laboratory performance of the LFTs in the current National HIV Testing Algorithm in Kenya. **Methods:** Four hundred blood samples, 145 HIV positives and 255 HIV negatives, were collected from the Regional Blood Transfusion Centers in Kenya. They were analyzed using five LFTs, three of which were in the HIV Testing Algorithm in Kenya. Samples were also tested using Vironostika™ Uni-Form II Ag/Ab ELISA as a Gold Standard. The decision on the HIV status of the samples was determined by consensus status of the five LFTs. Diagnostic sensitivity (D-SN), specificity (D-SP), Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were then computed together with relative Analytical sensitivity each LFT. **Results:** The three LFTs in the HIV Testing Algorithm in Kenya (KHB Colloidal Gold, First Response™ 1-2.0 and Uni-Gold™ HIV test) showed a D-SN of 100% (95% CI: 97.4-100.0), 96.4% (95% CI: 91.8 - 98.8) and 100% (95% CI: 97.4-100.0) respectively in relation to the Consensus status with LFTs. However, Determine™ HIV-1/2 showed the highest Analytical sensitivity when compared with two other kits in HIV Testing Algorithm in Kenya and Aware™ HIV-1/2 BSP kit. **Conclusion:** Though the LFTs in the current HIV Testing Algorithm in Kenya show high performance profiles, Determine™ HIV-1/2 showed higher Analytical sensitivity profile than the two HIV Screening and confirmation test kits. There is a need of reconsidering the financial savings (of 10-16%) vis-à-vis the possibilities of missing HIV positive cases in the current HIV Testing Algorithm in Kenya.