Abstract

Objective To compare the performance of the Focus HerpeSelect-2 enzyme immunoassay (EIA) to the gold standard HSV-2 Western blot, among HIV-1 uninfected men and women in East and Southern Africa. Methods 3399 HIV-1 uninfected women and men from 7 countries in East and Southern Africa were tested for HSV-2 antibody using Focus HerpeSelect-2 EIA. The performance of the HerpesSelect-2 EIA was compared with the gold standard HSV-2 specific Western blot. Results Two-thirds (2294/3399) of participants were male and two-thirds (2242/3399) were from East Africa. By Western blot testing, HSV-2 prevalence was 68%, 59% in men and 85% in women. At the manufacturer's recommended cut-off value of greater than 1.1, the HerpeSelect-2 EIA had a sensitivity of 98.3% and specificity 80.3%. Receiver operating characteristic (ROC) plot analysis indicated that the optimum cut-off was 2.1 or greater with sensitivity 93.9% and specificity 90.5%. Diagnostic accuracy was modestly higher for Southern Africa (AUC=0.979, 95% CI: 0.970-0.988) compared with East Africa (AUC=0.954, 95% CI: 0.942-0.965; $p<0.001$ for Southern vs. East Africa). Conclusions The Focus HerpeSelect-2 EIA has acceptable diagnostic accuracy for determination of HSV-2 serostatus in African HIV-1 uninfected adults. An assay cut-off value of 2.1 or greater results in approximately 90% sensitivity and specificity, against a gold standard HSV-2 Western blot. Diagnostic accuracy differed slightly by geographical region..