

## **Abstract**

**Objective** To compare the performance of the Focus HerpeSelect-2 enzyme immunoassay (EIA) with the gold standard herpes simplex virus (HSV) type 2 western blot, among HIV-1-uninfected men and women in east and southern Africa.

**Methods** 3399 HIV-1-uninfected women and men from seven countries in east and southern Africa were tested for HSV-2 antibody using the Focus HerpeSelect-2 EIA. The performance of the HerpeSelect-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 of 80.3%. Receiver operating characteristic 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 (area under the curve (AUC) 0.979, 95% CI 0.970 to 0.988) compared with east Africa (AUC 0.954, 95% CI 0.942 to 0.965;  $p < 0.001$  for southern vs east Africa).

**Conclusions** The Focus HerpeSelect-2 EIA has acceptable diagnostic accuracy for the 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.