

Validation of a modified commercial enzyme-linked immunoassay for detection of human immunodeficiency virus type 1 immunoglobulin G antibodies in saliva

Abstract:

This study was performed to evaluate the performance of a saliva collection device (OmniSal) and an enzyme-linked immunoassay (EIA) designed for use on serum samples (Detect HIV1/2) to detect human immunodeficiency virus type 1 (HIV-1) antibodies in the saliva of high-risk women in Mombasa, Kenya. The results of the saliva assay were compared to a "gold standard" of a double-EIA testing algorithm performed on serum. Individuals were considered HIV-1 seropositive if their serum tested positive for antibodies to HIV-1 by two different EIAs. The commercial serum-based EIA was modified to test the saliva samples by altering the dilution and lowering the cutoff point of the assay. Using the saliva sample, the EIA correctly identified 102 of the 103 seropositive individuals, yielding a sensitivity of 99% (95% confidence interval [CI], 94 to 100%), and 96 of the 96 seronegative individuals, yielding a specificity of 100% (95% CI, 95 to 100%). In this high-risk population, the positive predictive value of the assay was 100% and the negative predictive value was 99%. We conclude that HIV-1 antibody testing of saliva samples collected with this device and tested by this EIA is of sufficient sensitivity and specificity to make this protocol useful in epidemiological studies