Abstract #24

Performance of Bio-Rad Genetic Systems HIV-1/HIV-2 Plus O EIA followed by Multispot in a Dual Immunoassay HIV Testing Strategy

Abstract Category:	Laboratory-based Strategies Using Combinations of Screening Assays and Rapid Tests
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OBJECTIVE

To assess the performance of Bio-Rad Genetic Systems HIV-1/HIV-2 Plus O EIA (HIV-1/2 +O) followed by the Multispot HIV-1/HIV-2 rapid test for HIV-1 diagnosis.

METHODS

Specimens from HIV-infected and HIV-uninfected persons were obtained from two different sources. Serum Western blot HIV-1-positive specimens were obtained from HIV-infected persons enrolled in CDC's Validating Supplemental Testing to Confirm Preliminary Positive Rapid HIV Tests study. Enrollees of this study were from one of six study sites (Atlanta, Baltimore, Chicago, Denver, Louisville, and Philadelphia). They were 18-55 years of age, and had not been on antiretrovirals for at least 3 months. Plasma samples from HIV-uninfected persons were obtained from blood donors who tested EIA-negative (Abbott HIVAB HIV-1/HIV-2 (rDNA)) and pooled HIV-1 PCR-negative (Roche Ampliscreen). HIV-1-positive and negative specimens were tested with HIV-1/2 +O and Multispot. We report the specificity and sensitivity for HIV-1/2 +O and Multispot individually and together in the dual test strategy. We also report the concordance of Multispot results which were run in duplicate.

RESULTS

Among 302 persons known to be HIV-uninfected, there were 2 false-positive results on HIV-1/2 +O (specificity: 300/302=99.3%) and 7 false-positive results on Multispot (specificity: 295/302=97.7%). No specimens were false positive on both HIV-1/2 +O and Multispot (strategy specificity: 302/302=100%). Among 1065 HIV-infected persons, there were no false negative results on HIV-1/2 + O (sensitivity=1065/1065=100%) and 1 on Multispot (sensitivity 1064/1065=99.9%). The sensitivity of the dual test strategy was 1065/1065 (100%). Multispots (302 among HIV-uninfected persons and 1065 among HIV- infected persons) were the same as the initial result in all cases (i.e. non- reactive on both test runs or reactive on both test runs).

CONCLUSIONS

Data from this study indicate that a dual test strategy using HIV-1/2+O as the initial screening test followed by Multispot as a second test has high sensitivity and specificity. Though there were false positives using the HIV-1/2 +O screening test, no dual false-positive test results were observed using Multispot as a second test in the dual immunoassay strategy. Conducting the secondary screening test (Multispot) in duplicate did not appear to be beneficial.