

Evaluation of a Proposed Testing Strategy for Laboratory-Based Testing Using an HIV-1/2 Discriminatory Assay for HIV: Strategy 5 Data Needs

<i>Abstract Category:</i>	Emerging Dilemmas: HIV-2 Confirmation and Diagnosis in HIV Vaccine Recipients
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OBJECTIVE

To study the effectiveness of an algorithm using an HIV-1/2 discriminatory assay to identify the infection status of patients infected with HIV.

METHODS

Specimens were initially tested using the BioRad HIV-1/2 Plus O enzyme immunoassay (EIA); all reactive specimens were retested in duplicate. Those specimens that were reactive at least twice were tested using a discriminatory assay: BioRad Multispot HIV-1/2 rapid immunoassay. Those specimens determined to be HIV-1 were confirmed using the Genetic Systems HIV-1 Western blot (WB).

RESULTS

There were 64,690 serodiagnostic specimens tested from January 2006 through September 2007; 730 specimens were EIA HIV-1/2 reactive (1.1%). Multispot identified 620 of these specimens as HIV-1 (84.9%); 609 specimens were WB positive (83.4%), 9 WB indeterminate (1.2%), and 2 WB negative (0.3%). There were 110 EIA reactive specimens (15.1%) that were Multispot nonreactive for both HIV-1 and HIV-2; 92 specimens (12.6%) were WB negative and 18 specimens (2.5%) were WB indeterminate. There were 4 EIA reactive specimens that were initially Multispot reactive for both HIV-1 and HIV-2 (0.5%), but all were reactive for HIV-1 upon conducting the manufacturer's specified dilution analysis. No specimens were reactive for HIV-2. HIV-1 RNA testing was performed on 10 of 11 specimens that were EIA reactive and WB indeterminate or negative. For Multispot HIV-1 reactive specimens, 6 of the 8 WB indeterminate specimens tested (75%) were positive for HIV-1 RNA; the 2 WB negative specimens were RNA negative. For Multispot nonreactive specimens, only 1 of the 78 WB negative specimens tested (1.3%) and 1 of the 17 WB indeterminate specimens tested (5.9%) were positive for HIV-1 RNA.

CONCLUSIONS

The data needs for Strategy 5 were as follows: 1) 15.1% (110/730) of EIA HIV-1/2 reactive specimens were nonreactive on the HIV-1/2 discriminatory assay; 2) There were 4 specimens reactive to both HIV-1 and 2 but all were determined to be HIV-1; 3) There were no EIA HIV-1/2 reactive specimens that were negative on HIV-1 supplemental tests that were truly infected with HIV-2; and 4) There were no specimens reactive for HIV-2 on the HIV-1/2 discriminatory assay.