Abstract #50

Usefulness of a Secondary Enzyme Immunoassay (EIA) Screen in a Low HIV Prevalence Population

Abstract Category:	Laboratory-based Strategies Using Confirmatory Supplemental Tests or Combinations of Screening Assays
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OBJECTIVE

EIA screening for HIV is both sensitive and specific, however in low prevalence populations even extremely specific EIAs lead to unnecessary confirmatory testing. Study objectives were to calculate the number and percentage of initially reactive EIAs that were not reactive on repeat testing, and to evaluate signal to cut-off ratios as a substitute for secondary EIA screening.

METHODS

The US Army HIV diagnostic algorithm employs an initial screen with Genetic Systems rLAV (Bio-Rad Laboratories). Reactive samples are tested in duplicate with Vironostika HIV-1 Microelisa System (bioMerieux, Inc), then repeated reactive samples are subjected to Genetic Systems HIV-1 Western blot (WB) (Bio-Rad Laboratories). Test results from 2002-2007 were used to calculate the number and percent of initially reactive EIAs that were not repeat reactive, and EIA performance was compared to the final WB result. Samples with indeterminate WB results were excluded from analysis. EIA signal to cut-off ratios were used to assess the performance characteristics at various cut-off values using receiver-operating characteristics analysis.

RESULTS

The HIV prevalence by WB was 0.06% (4009/6,236,874). At initial screening, 16,415 (0.26%) specimens were reactive by rLAV (specificity = 99.8%; PPV = 24.4% [95% CI=23.8-25.1]). Of these specimens, 4,142 (25.2%) were reactive by one or both Vironostika EIAs (specificity = 98.9%; PPV = 96.8 [95% CI=96.2-97.3]). Use of secondary screening EIAs eliminated the need for 98.9% of unnecessary WB's. Positive predictive value (PPV) increased significantly from 16.3% in 2002 to 39.1% in 2007 for rLAV and from 96.6% in 2002 to 97.5% in 2007 for Vironostika ($p<0.001$). Secondary screening PPV was not significantly different when using a single EIA as compared to using the criterion of one or both EIAs being positive. The best cut-off for EIA rLAV was > 3.79 (sensitivity = 99.6%, specificity = 99.8%, LR for a positive test = 407.1, PPV = 94.0%).

CONCLUSIONS

The PPVs of initial rLAV and secondary in-duplicate Vironostika screening were 24.4% and 96.8% in this population. Secondary EIA screening substantially reduces the number of unnecessary confirmatory tests required, and should continue to be the standard for laboratory based testing algorithms in low HIV prevalence populations.