Abstract #27

Comparative Performance of Dual 3rd Generation Immunoassays as a Potential Laboratory-Based HIV-1/2 Testing Strategy

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BACKGROUND

HIV-1 Western Blot and Immunofluorescense (IFA) assays have fulfilled national guidelines for supplemental testing in the confirmation process of an HIV-1 infection since they were established in the mid-1980s. However, as HIV-1/2 screening assays have increased in sensitivity and traditional supplemental assays have remained relatively constant in sensitivity, there is a potential for discordant results among acute and early HIV infected individuals. The purpose of this study was to evaluate the clinical performance of dual 3rd generation immunoassays in sequential use to screen and confirm the presence of HIV-1 antibodies as compared to traditional CDC/APHL recommended laboratory-based algorithms.

METHODS

In an effort to maximize the sensitivity and specificity of the proposed strategy, immunoassays with different antigen sources and/or binding/detection methods would be preferred. The selected immunoassays were Bio-Rad's HIV-1/2 Plus O EIA (enzyme immunoassay) with its direct antibody sandwich technique and Siemen's Advia HIV-1/O/2 CIA (chemiluminescent immunoassay) with its antigen bridging format. Both assays are FDA approved for diagnostic use. 2,765 prospective fresh serum samples were tested by both 3rd generation immunoassays. 92 samples were confirmed seropositive (3.3%) [Western Blot (90) or NAAT (1) positive results or subsequent seroconversion(1)]. Since the sensitivity of an algorithm is dictated by the initial screening assay, the sensitivity and specificity of each immunoassay was determined independently to determine if one assay has an advantage over the other in a dual testing strategy. In addition, the clinical sensitivity and specificity of the dual immunoassays, as a combined strategy, was compared to a traditional 3rd generation EIA/Western Blot algorithm (reference method).

RESULTS

The sensitivity of each immunoassay was 100% (92/92) and the specificity of each assay was 99.77% (2667/2673) suggesting that either assay would be suitable for the initial screening assay. Since both assays shared four false positive specimens, regardless of the assay arrangement in the strategy, the sensitivity and specificity of the dual 3rd generation testing strategy was 100% and 99.85% (2669/2673), respectively. The sensitivity of the 3rd generation EIA/Western Blot strategy was 97.8% (90/92) and the specificity was 100% (2673/2673).

CONCLUSIONS

The dual 3rd generation immunoassay strategy demonstrated increased sensitivity over that of the reference method, increased specificity over either 3rd generation immunoassay in stand-alone use and comparable specificity to the licensed HIV-1 Western Blot, the licensed HIV-1 NAAT assay and several POC HIV-1/2 rapid tests. The dual 3rd generation immunoassay strategy has the potential to decrease testing turn-around-time on seropositive results as well as decease costs to an estimated 26-43% of the reference method per seropositive result.