Abstract #36

Detection of Acute and Chronic HIV Infections by an HIV Antigen/Antibody Combination Assay

Abstract Category:	New HIV Diagnostic Technologies Including Those That Are Not FDA Approved
Primary Author:	Richard Vickstrom
Affiliation:	Abbott Diagnostics, Abbott Park, IL
Co-Authors:	J. Hackett, Jr., P. Swanson, D. West, J. Jacob, M. White, S. Devare, G. Schochelman, G. Williams, C. Brennan

BACKGROUND

Individuals with acute HIV infection (antibody (Ab)-negative) have a substantially elevated risk of transmission and represent an important driver of the ongoing epidemic. Reliable and cost-effective methods to detect acute infections have important implications for HIV prevention strategies. The ARCHITECT® HIV Ag/Ab Combo assay, in development for the US (not FDA approved), is a two-step chemiluminescent microparticle immunoassay for the simultaneous qualitative detection of HIV p24 antigen (Ag) and antibodies to HIV-1 groups M and O, and HIV-2.

METHODS

This study assessed the performance of the ARCHITECT HIV Ag/Ab Combo assay for specificity, sensitivity, and imprecision by testing specimens from diagnostic patients, blood donors, known Ab positive HIV-1 group M (N=500), O (N=65), and HIV-2 (N=125) infections, HIV-1 p24 Ag, and HIV seroconversion panels. In addition, we determined the viral RNA level corresponding to the cutoff of the Combo assay and assessed performance on genetically divergent HIV-1 strains.

RESULTS

The ARCHITECT HIV Ag/Ab Combo assay demonstrated 100% Ab sensitivity with HIV-1 group M , O, and HIV-2 specimens. Compared to HIV Ab assays, the assay showed earlier detection for 8 of 10 seroconversion panels tested, reducing the seroconversion window by 0 to 9 days. HIV p24 Ag sensitivity was < 20 pg/mL based on the AFSSAPS panel and no subtype-related differences in sensitivity were observed for 38 unique HIV-1 group M and O isolates. Observed specificity for the Combo assay was 99.55% (2460/2471) for diagnostic and 99.95% (1999/2000) for donor specimens. Total imprecision (within run, between run, and between day) ranged between 3.5% to 8.4%. An S/CO of 1.0 in the Combo assay corresponded to 13,000, 18,000, and 30,000 RNA copies/ml based on the AMPLICOR HIV-1 MONITOR v1.5, VERSANT HIV-1 RNA 3.0, and Real Time HIV-1 assays, respectively.

CONCLUSIONS

The ARCHITECT HIV Ag/Ab Combo assay demonstrated sensitive detection of HIV p24 antigen and antibodies across divergent HIV strains and earlier detection of acute infections than HIV Ab assays. With automation, individual sample testing, high throughput, and excellent specificity, the ARCHITECT HIV Ag/Ab Combo assay provides a cost-effective alternative to pooled nucleic acid testing strategies for detection of acute HIV infections.