#### Abstract #18

# Incorporation of the Aptima® HIV-1 RNA Assay into Serodiagnostic and Rapid Test Confirmation Testing Algorithms to Resolve Discordant Serological Results

	Laboratory-based Strategies Using Confirmatory Supplemental Tests or Combinations of Screening Assays
Primary Author:	Monica Parker
Affiliation:	New York State Department of Health, Albany, NY
Co-Authors:	R. Boromisa, T. Sullivan, M. San Antonio-Gaddy, A. Richardson-Moore

### **PROJECT**

To develop test algorithms and interpretations using nucleic acid testing to resolve discordant serological test results and confirm HIV-1 infection status.

# **ISSUES**

During 2006 and 2007, 123 of 715 (17%) EIA rapid reactive (RR) serodiagnostic specimens and 180 of 544 (33%) rapid test preliminary positive (PP) specimens were either negative or indeterminate by Western blot (WB). Follow-up specimens are recommended, but inconclusive results may persist upon repeat testing or no follow-up specimen may be obtained, leaving HIV-infection status of the individual unresolved. Our laboratory has run Gen-Probe's Procleix® and Aptima® HIV-1 RNA assays since 2005 as part of a CDC-sponsored study to identify primary HIV infections through screening of pooled seronegative specimens. In 2007, we implemented the use of the Aptima® HIV-1 RNA assay on individual specimens to resolve inconclusive serologic test results in our routine testing. Data from RNA testing conducted between January and September 2007 are presented here.

#### **RESULTS**

Of 20 EIA RR/WB non-positive serodiagnostic specimens (6 WB indeterminate and 14 WB negative) that underwent RNA testing, none had a reactive HIV-1 RNA test. Of 17 rapid test PP/WB non-positive specimens, 7 of 7 (100%) WB indeterminate and 1 of 10 (10%) WB negative specimens had a reactive HIV-1 RNA test. Follow-up testing was recommended for clients with RNA-positive specimens to obtain WB confirmation, but was not recommended for clients with RNA-negative specimens unless warranted by risk factors. Algorithms using the Aptima® HIV-1 RNA assay for serodiagnostic and rapid test confirmation and additional data from 2006 will be presented.

## LESSONS LEARNED

The Aptima HIV-1 RNA assay is being used in our laboratory to resolve discordant serological test results and identify HIV infection prior to complete seroconversion. Our ability to incorporate the Aptima® test into routine testing algorithms has been aided by our participation in primary HIV infection studies whereby a consistent specimen load offsets costs associated with sporadic testing of individual specimens. Additionally, specimens submitted to our laboratory for serological testing are collected and handled in a manner appropriate for RNA testing. These preliminary data suggest that the costs and benefits of RNA testing in routine algorithms warrant further study.