Abstract #18

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

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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.