

Evaluation of an FDA-approved qualitative RNA detection assay for diagnosis of HIV-1 infection in perinatally exposed infants

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Objective: Our objective was to evaluate an FDA-approved qualitative RNA detection assay for diagnosis of HIV-1 infection in perinatally exposed infants.

Methods: From 1995 to 2008, the New York State Department of Health's Pediatric HIV Testing Service conducted diagnostic testing of perinatally exposed infants using a laboratory-developed proviral DNA PCR assay. In this retrospective evaluation, a total of 96 archived specimens collected from infants who were previously confirmed as HIV-1 positive or negative by testing of sequential specimens were tested using the APTIMA[®] HIV-1 RNA Qualitative Assay (Gen-Probe, San Diego, CA). Results were compared to previous DNA PCR results.

Results: Of 61 DNA PCR-positive specimens tested, all 61 (100%) were positive by the RNA assay. Of 35 DNA PCR-negative specimens, 28 were negative and 7 were positive by the RNA assay. All 7 RNA-positive/DNA PCR-negative specimens, including 2 from the same infant, were early specimens from infants who were later confirmed as HIV-1 positive by DNA PCR testing of follow-up specimens. For these 6 infants, the first HIV-1 RNA-positive specimen was collected an average of 27.7 days (range 18-65) earlier than the first DNA PCR-positive specimen. The 28 specimens that were negative by both the DNA PCR and the RNA assay were true negatives based on established criteria for excluding HIV-1 infection in perinatally exposed infants. The RNA assay was also conducted on a subset of specimens using 100 µl of patient plasma, rather than 500 µl as recommended by the manufacturer. All HIV-positive specimens tested using 100 µl of patient plasma were positive at this reduced specimen volume.

Conclusions: Our results indicate that the APTIMA[®] HIV-1 RNA Qualitative Assay is well suited for diagnostic testing of perinatally exposed infants. In addition, the volume of infant specimens is often limited and we have demonstrated that the assay can be used reliably with a reduced specimen volume.