Validation of the GEN-PROBE® APTIMA® HIV-1 RNA Qualitative Assay for use with Dried Blood Spots (DBS)

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Background

The Wadsworth Center performs Western blot testing on dried blood spots (DBS) submitted by community-based HIV rapid testing sites to confirm reactive HIV rapid tests. When antibodies do not confirm, there are no additional tests available to resolve the discordance. This issue has become particularly relevant as many sites have begun to use the Alere Determine™ HIV Ag/Ab rapid test which can detect early HIV-1 infections well before the Western blot will be positive. Therefore, we sought to validate the APTIMA® HIV-1 RNA Qualitative Assay for use with DBS specimens.

Methods

• HIV-1 RNA was detected in 90% HIV-1 antibody-positive DBS.
• HIV-1 RNA was not detected in any HIV-1 negative DBS.

Results

Conclusions

• APTIMA® HIV-1 RNA Qualitative Assay detect HIV-1 RNA in DBS specimens with at least 5000 RNA copies/ml.
• Storing DBS at elevated temperatures for 21 days had no effect on the LOD for the assay.
• Testing of HIV-positive DBS prepared from clinical blood samples was 90% accurate.
• Testing DBS using the APTIMA assay is feasible, but the LOD relative to plasma and serum should be clearly noted when reporting negative results.

Works Cited