Performance Evaluation of the Aptima® HIV Quant Dx and Aptima® HBV Quant assays on the fully automated Panther in comparison to COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 and HBV tests

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Background
Quantification of HIV-1 RNA and HBV DNA viral load plays a central role in clinical management of HIV and HBV infected patients, before and during antiretroviral therapy. The Hologic Aptima® HIV-1 Quant Dx assay and HBV Quant assay are commercially available quantitative assays.

Method comparison

**HIV**

191 plasma samples (94 prospective and 97 retrospective) from HIV-1 infected patients were tested using Aptima® HIV-1 Quant Dx Assay, based on HIV viral load, as determined by routine testing using COBAS® TaqMan® HIV-1 test.

**HBV**

200 plasma or sera samples (100 prospective and 100 retrospective) from HBV-infected patients were tested for Aptima® HBV Quant Assay, based on HBV viral load, as determined by routine testing using COBAS® TaqMan® HBV test.

Analytic performance with reference panel

**HIV**

Qnostics HIV-1 50949 and Bio QControl P0043 HIV-RNA were used to assess reproducibility and precision.

**HBV**

Qnostics 14038 HBV and Bio QControl P0041 HBV DNA were used to assess reproducibility and precision.

Conclusions

The Hologic Aptima® HIV-1 Quant Dx assay and Aptima® HBV Quant assays as performed on the fully automated Panther system gave highly comparable performance to that of Roche COBAS® TaqMan® HIV-1 v2 and HBV v2.0 assays for clinical samples. Excellent results were observed using commercially available panels indicating high sensitivity and very good reproducibility.

This system, using 0.5 ml sample input on primary samples, was easy to use and could generate 120 test results in less than four hours.