# Performance Evaluation of the Aptima® HIV-1 Quant Dx and Aptima® HBV Quant assays on the fully automated Panther in comparison to Cobas® 6800/8800 HIV-1 and HBV tests

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## Background

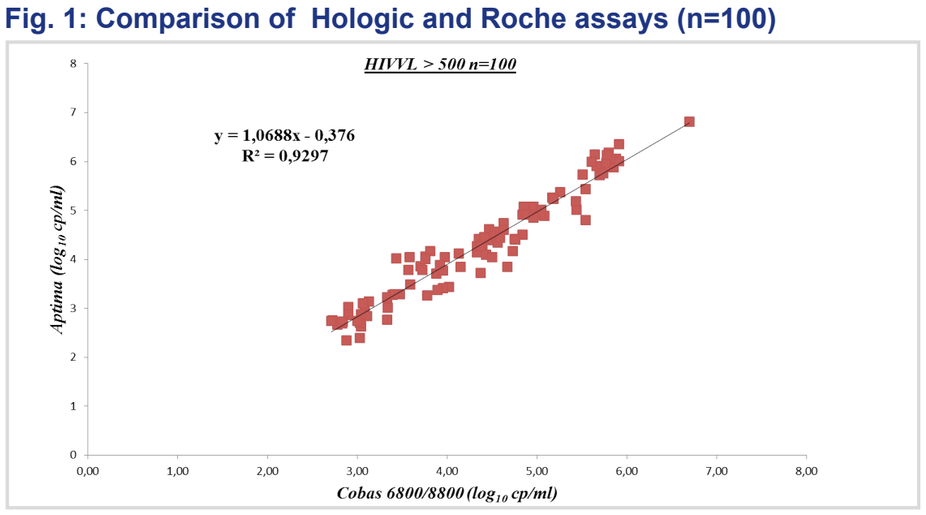
Quantification of HIV-1 and HBV viral load plays a key role in management of HIV and HBV patients. Aptima® HIV-1 Quant Dx and HBV Quant are run on Panther system. The assays are based on TMA technology. Clinical results obtained with Aptima were compared to Cobas® 6800/8800 HIV-1 and HBV results.

## Assay performance

### Method comparison

**HIV** 100 retrospective frozen plasma specimens from HIV infected patients with a viral load exceeding 500 copies/ml were tested using Aptima® HIV-1 Quant Dx Assay, based on HIV viral load, as determined by routine testing using Cobas® 6800/8800 HIV-1 test.

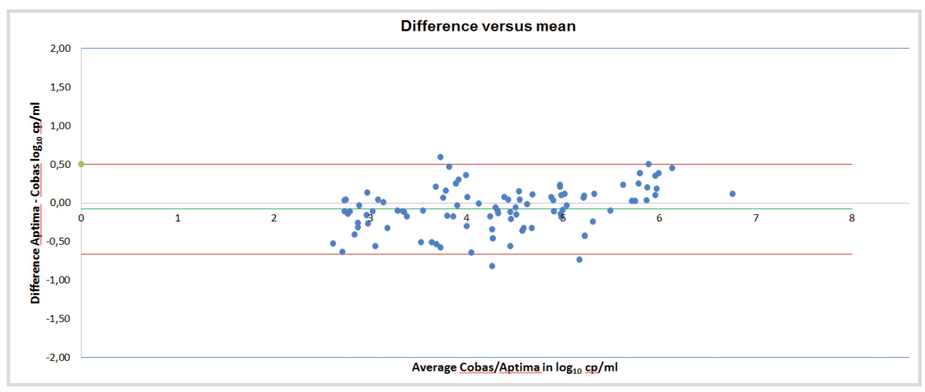
**Fig. 1: Comparison of Hologic and Roche assays (n=100)**





- **Deming regression was excellent between the 2 assays for 100 quantifiable samples : y =1.068x-0.376**
- **Regression coefficient was close to 1 $R^2$ = 0.93**

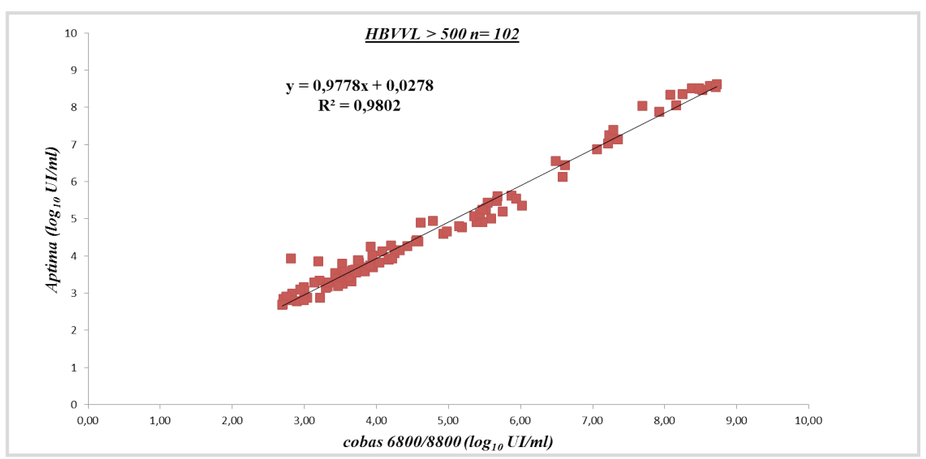
**Fig. 2: Bland Altman plot comparing the quantitative results (> 500 cp/ml) from 100 clinical samples tested in Aptima® HIV-1 Quant Dx assay and the Cobas® 6800/8800 HIV-1 test**




**None of the tested samples differed by more than 1 log between the 2 assays**

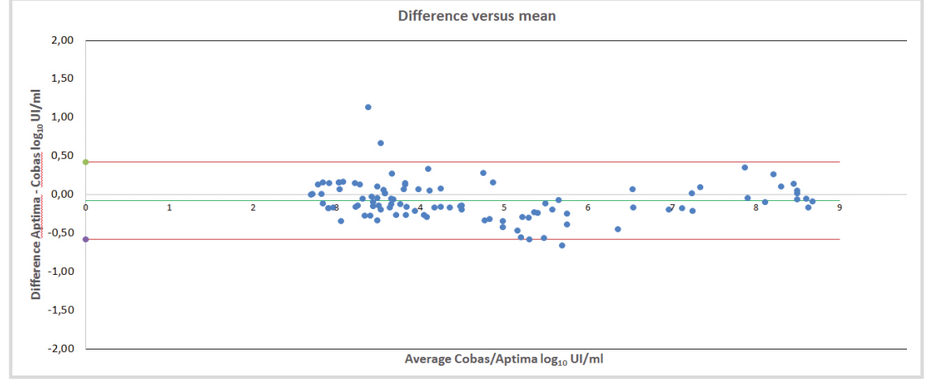
**HBV** 102 retrospective plasma or serum specimens from HBV infected patients with a viral load exceeding 500 UI/ml were tested for Aptima® HBV Quant Assay, based on HBV viral load, as determined by routine testing using Cobas® 6800/8800 test.

**Fig. 3: Comparison of Hologic and Roche assays (n=102)**




- **Deming regression was excellent between the 2 assays for 102 quantifiable samples : y =0.98 x+0.0278**
- **Regression coefficient was close to 1 ($R^2$ = 0.98)**

**Fig. 4: Bland Altman plot comparing the quantitative results (> 500 UI/ml) from 102 clinical samples tested in Aptima® HBV Quant assay and the Cobas® 6800/8800 HBV test**




**Only one sample differed in viral load result by more than 1 log (1.13) between the 2 assays, giving higher result (3.94 log) with Aptima test than with Roche test (2.81 log)**

### Assessment of repeatability and reproducibility

**HIV**
- Home made low and high level controls were used to assess repeatability
- Panels were obtained by pooling patient plasma samples and diluting to obtain the expected viral load value

**Tab.1: Assessment of HIV repeatability**

| | n | Mean ($log_{10}$ cp/ml) | SD ($log_{10}$ cp/ml) |
|---|---|---|---|
| Internal control | 10 | 2.67 | 0.11 |
| High positive pool | 10 | 6.66 | 0.05 |

- **Repeatability assessed by testing quality controls 10 times in the same run was excellent with Standard Deviation (SD) ranging from 0.05 to 0.11 $log_{10}$ cp/ml**

- Home made internal quality control, and Aptima High (HPC) and Low (LPC) Positive control from the kit were used to assess reproducibility

**Tab.2: Assessment of HIV reproducibility**

| | n | Mean ($log_{10}$ cp/ml) | SD ($log_{10}$ cp/ml) |
|---|---|---|---|
| Internal control | 30 | 2.62 | 0.13 |
| LPC | 30 | 2.82 | 0.11 |
| HPC | 30 | 5.04 | 0.06 |

- **Reproducibility assessed by testing quality controls 30 times in different experiments was excellent with Standard Deviation (SD) ranging from 0.06 to 0.13 $log_{10}$ cp/ml**

**HBV**
- Home made low and high level controls were used to assess repeatability
- Panels were obtained by pooling patient plasma samples and diluting to obtain the expected viral load value

**Tab.3: Assessment of HBV repeatability**

| | n | Mean ($log_{10}$ UI/ml) | SD ($log_{10}$ UI/ml) |
|---|---|---|---|
| Internal control | 10 | 3 | 0.11 |
| High positive pool | 10 | 7.79 | 0.04 |

- **Repeatability assessed by testing quality controls 10 times in the same run was excellent with Standard Deviation (SD) ranging from 0.04 to 0.11 $log_{10}$ UI/ml**

- Home made internal quality control, and Aptima High (HPC) and Low (LPC) Positive control from the kit were used to assess reproducibility

**Tab.4: Assessment of HBV reproducibility**

| | n | Mean ($log_{10}$ UI/ml) | SD ($log_{10}$ UI/ml) |
|---|---|---|---|
| Internal control | 30 | 2.94 | 0.07 |
| LPC | 30 | 2.77 | 0.09 |
| HPC | 30 | 4.49 | 0.06 |

- **Reproducibility assessed by testing quality controls 30 times in different experiments was excellent with Standard Deviation (SD) ranging from 0.06 to 0.09 $log_{10}$ UI/ml**

### Cross contamination

No cross contamination (neither with HIV nor with HBV) was observed when testing 5 consecutive runs using negative control and High positive control samples alternately.

## Conclusion

**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® 6800/8800 HIV-1 and HBV assays for tested clinical samples. Good results were observed using home made and Aptima controls indicating good reproducibility and repeatability.**
**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.**

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