A comparative evaluation of Aptima HBV Quant and Aptima HCV Quant Dx assays with COBAS TaqMan HBV and HCV v2.0 (CAP/CTM) in patients affected by chronic hepatitis

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Background

Viral hepatitis has emerged as a major public health problem throughout the world affecting several hundreds of millions of people. Hepatitis B virus (HBV) and Hepatitis C virus (HCV) can produce a chronic infection that is associated with an increased risk for chronic liver disease and hepatocellular carcinoma.

Patients with chronic hepatitis B need the monitoring of viral load, in order to assess the disease status and response to therapy. For patients affected by HCV infection, quantitative HCV RNA testing is recommended prior to the initiation and during the antiviral therapy to document the level of viremia.

The aim of this study is to evaluate the performance characteristics of Hologic Aptima HBV Quant and Aptima HCV Quant Dx assays performed on the Panther system in comparison to Roche COBAS® TaqMan HBV and HCV v2.0 (CAP/CTM).

Methods

The Aptima HBV and HCV assay is a real-time transcription mediated amplification test for the detection and quantification of HBV DNA and HCV RNA in fresh and frozen human serum and plasma.

Aptima HCV Quant Dx is able to quantify with equal efficiency HCV genotypes 1-6 with a precision of LLOQ (Lower Limit of Quantification) of 10 IU/mL while CAP/CTM has a LLOQ of 15 IU/mL. The targets are highly conserved 5'UTR sequences. Aptima HBV Quant is able to quantify HBV genotypes A-H with a precision of LLOQ of 10 IU/mL, using a dual target (s and pol gene), while CAP/CTM has a LLOQ of 20 IU/mL.

The correlation between quantitative results was evaluated by using the linear regression analysis and Bland–Altman plot (Fig. 1).

We tested 579 samples from positive patients: 220 HBV and 359 HCV. A minimum volume to test in single with each assay was 1.85 mL: 0.75mL for Aptima and 1.1 mL for CAP/CTM.

Results

In the selected population, there was an 80.5% agreement with an overall detection rate of 140/220 (63.6%) for Aptima HBV and 144/220 (65.5%) for CAP/CTM HBV. Among 80 samples not detected by Aptima HBV, 16 were detected by CAP/CTM. Vice versa, out of 76 samples not detected by CAP/CTM HBV, 12 were detected by Aptima HBV. Moreover, 14 samples detected by Aptima HBV were quantified by CAP/CTM HBV (Table 1).

For HCV there was a 97.4% agreement with an overall detection rate of 145/349 (41.5%) for Aptima HCV and 146/349 (41.8%) for CAP/CTM HCV. Among 204 samples not detected by the Aptima HCV, 3 were detected by CAP/CTM. Vice versa, out of 203 samples not detected by CAP/CTM HCV, 1 was detected and 1 was quantified by Aptima HCV. Moreover, 4 samples detected by Aptima HCV were quantified by CAP/CTM HCV (Table 2).

Table 1. Results of study for HBV

HBV Detection Rate

ROCHE	APTIMA ND	APTIMA Detected	APTIMA Quant	Total	% Agree
TND	64	12		76	84,2
Detected	16	18	1	35	51,4
Quant		14	95	109	87,2
Total	80	44	96	220	

Overall Detection Rate: Roche = 144/220 (65,5%) - HOLOGIC = 140/220 (63,6%)

Table 2. Results of study for HCV

HCV Detection Rate

ROCHE	APTIMA ND	APTIMA Detected	APTIMA Quant	Total	% Agree
TND	201	1	1	203	99,0
Detected	3	6		9	66,7
Quant		4	133	137	97,1
Total	204	11	134	349	

Overall Detection Rate: Roche = 146/349 (41,8%) - HOLOGIC = 145/349 (41.5%)

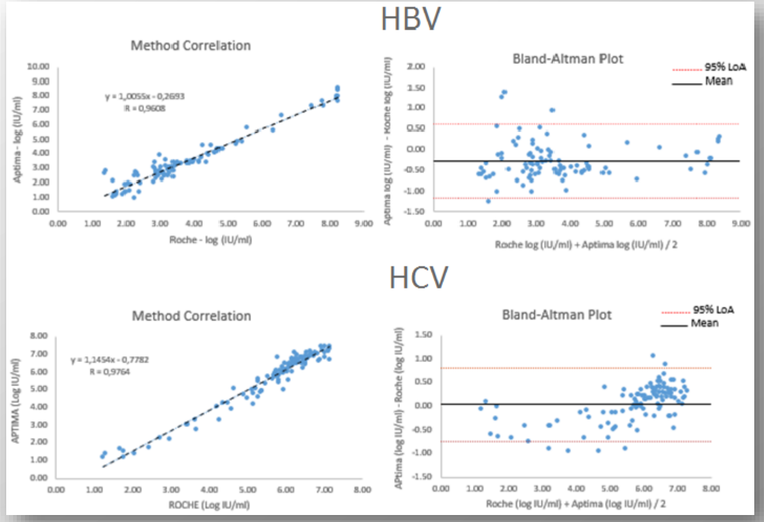

Fig. 1 The linear regression analysis and Bland–Altman plot of the platform comparisons.

Conclusions

The Aptima HBV and HCV assay demonstrated high efficiency and an excellent accuracy for the detection and quantification of chronic hepatitis B and C virus in comparison to CAP/CTM. Along with excellent performance, the full automation, ease of use, and improved workflow are significant for both instruments.

It is noteworthy that Aptima HBV could be more specific than CAP/CTM, due to the dual target amplification and the specific capture method.

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