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EVALUATION OF PERFORMANCES OF VERSANT HCV RNA 1.0 ASSAY (kPCR) AND ROCHE COBAS AmpliPrep/COBAS TaqMan HCV TEST v2.0 AT LOW LEVEL VIREMIA

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Introduction

The primary goal of anti-HCV therapy is achievement of a sustained virological response which indirectly means eradication of the viral infection.
The most recent viral load assays generally use real time (RT) polymerase chain reaction technology and have limit of detection (LOD) between 12 and 15 IU/ml. Furthermore results can be reported as target not detected (TND) or < LOD but detectable (TD). Since assessing rapid virological response is used for guiding treatment duration, the accuracy of assay to detect low levels of viremia is critical to carefully define the treatment response.
The objective of this analysis was to assess the concordance between low level HCV values obtained using two RT PCR assays.

VERSANT HCV RNA 1.0 Assay (kPCR)
(Siemens Healthcare Diagnostics, Tarrytown, NY, US)

Roche COBAS AmpliPrep/COBAS TaqMan HCV Test v2.0
(CAP/CTM, Roche Molecular System, Pleasanton, CA, US)

Methods

One hundred forty-two serum samples with HCV RNA ranged from "TND" to 600 IU/ml were assessed using VERSANT HCV RNA 1.0 Assay (kPCR) (Siemens Healthcare Diagnostics, Tarrytown, NY, US) and Roche COBAS AmpliPrep/COBAS TaqMan HCV Test v2.0 (CAP/CTM, Roche Molecular System, Pleasanton, CA, US). Both assay have a LOD of 15 IU/ml. Simple regression analysis was used to assess the correlation between the HCV RNA levels by the CAP/CTM and VERSANT kPCR assays. The average Log difference and the consistency in the difference between the assays were analyzed using Bland- Altman plot.

Conclusions

A low correlation was found between the two assays in the evaluation of samples selected in a very low viremia range where it's known that assays loose precision. A difference was observed between them in the assessment of values below LOD. The study is in progress to determine the accuracy of the assays.

Results

Analysis of the correlation between the real-time PCR assays, revealed that HCV RNA viral load measured by VERSANT kPCR weakly correlated with that of the CAP/CTM (R = 0.644, P < 0.0001) (figure 1). A Bland–Altman plot of the 82 paired results revealed a mean difference of 0.13 log IU/mL (95% CI: 0.05 to 0.21) in HCV RNA levels obtained between the two assays, with 95% of the individual differences falling within the range of -0.60 to 0.86 Log IU/mL. In this analysis results below the limit of quantification (n.60) were excluded (figure 2).

Figure 1

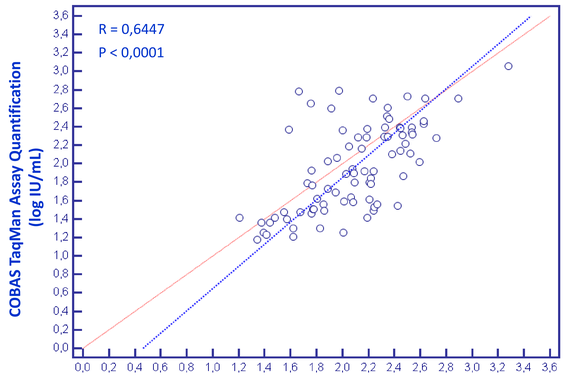
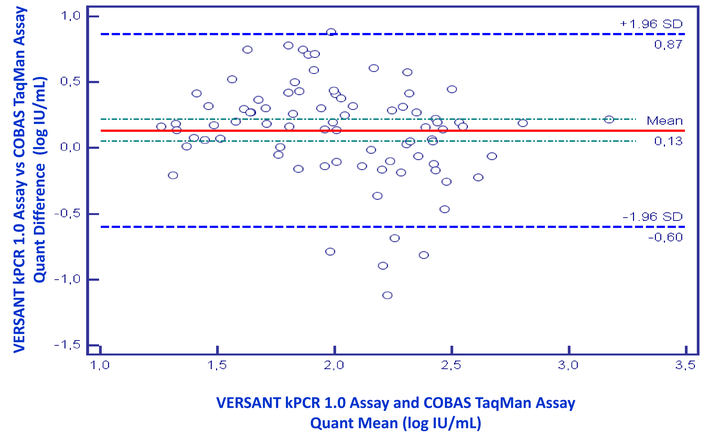


Figure 2



		ROCHE ASSAY		
		Not detected	<15 IU/mL, but detected	≥15 IU/mL
SIEMENS ASSAY	Not detected	**9**	**12**	**1**
	<15 IU/mL, but detected	**3**	**12**	**2**
	≥15 IU/mL	**2**	**19**	**82**

Table 1

Then an analysis of the overall concordance between CAP/ CTM and VERSANT kPCR was performed (table 1). Of the 142 samples, HCV RNA was negative in 9, <LOD but detectable in 12 and positive in 82 by both assays. However, 5 of the 14 samples HCV RNA negative (TND) by CAP/CTM were positive by VERSANT kPCR (3: <LOD but TD; 2: >15 IU/ml). Similarly, 13 of the 22 samples HCV RNA negative by VERSANT kPCR were positive by CAP/CTM (12: <LOD but TD; 1: >15 IU/ml). Further, 19 samples <LOD but detectable by CAP/CTM were quantifiable by VERSANT kPCR.