Method Comparison between the VERSANT HCV RNA 1.0 Assay (kPCR), Abbott RealTime HCV, Roche COBAS AmpliPrep/COBAS TaqMan HCV Test, and VERSANT HCV RNA 3.0 Assay (bDNA)

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Abstract

Objective: To compare the VERSANT HCV RNA 1.0 Assay (kPCR), Abbott RealTime HCV, Roche COBAS AmpliPrep/COBAS TaqMan HCV Test, and VERSANT HCV RNA 3.0 Assay (bDNA) for the quantification of HCV RNA in serum and plasma of HCV-infected individuals over the range of 15 to 1,000,000 IU/mL using the VERSANT HCV RNA Molecular System. The assay was intended to be used in conjunction with clinical presentation and other laboratory markers of disease to aid in the management of HCV-infected individuals undergoing antiviral therapy.

Background

The VERSANT HCV RNA 1.0 Assay (kPCR) is an in vitro nucleic acid amplification assay for the detection of HCV RNA in serum and plasma of HCV-infected individuals over the range of 15 to 1,000,000 IU/mL using the VERSANT HCV RNA Molecular System. The assay is intended to be used in conjunction with clinical presentation and other laboratory markers of disease to aid in the management of HCV-infected individuals undergoing antiviral therapy. The range of 15 to 1,000,000 IU/mL is called the “reporting range” and is the concentration range of HCV RNA in serum or plasma that the assay is intended to measure.

Materials and Methods

Equipment and software

The VERSANT HCV RNA Molecular System consists of a Sample Preparation (SP) module and an Amplification/Detection (AD) module, along with associated software (Figure 1). Samples, calibrators, and controls are extracted on the SP module and amplified and detected on the AD module. The AD module consists of two channels: the TaqMan channel and the bDNA channel. The TaqMan channel is used for amplification and detection of HCV RNA using the TaqMan HCV Test. The bDNA channel is used for amplification and detection of HCV RNA using the VERSANT HCV RNA 3.0 Assay (bDNA).

Sample collection

A total of 156 HCV-infected specimens were collected and tested for the purpose of this study. Samples were collected from BioCollections Worldwide, Inc. (Miami, FL, U.S.) and SeraCare Life Sciences, Inc. (Milford, MA, U.S.). Specimens were included if they were shown to be HCV-positive in the absence of co-infection and/or HCV RNA. Each sample was tested in singlicate with each of three unique HCV kit lots.

Sample processing

VERSANT HCV RNA Assay (kPCR) was used to measure 156 IU/mL or 100 IU/mL of sample input volumes to extract 0.2 mL of sample and 0.3 mL of sample input volumes to extract 0.4 mL of sample. Kits were used and SP processing was performed at BioCollections Worldwide, Inc. (Miami, FL, U.S.) and at SeraCare Life Sciences, Inc. (Milford, MA, U.S.). SP processing was performed at BioCollections Worldwide, Inc.

Data analysis

A scatter plot showing the VERSANT HCV RNA 1.0 Assay (kPCR) log quantitation versus that of the comparator assay was drawn for each set of paired quantitations. The linear relationship between VERSANT HCV RNA 1.0 Assay (kPCR) and the comparator methods was established using Deming regression.

Results

The VERSANT HCV RNA 1.0 Assay (kPCR) with that of the Abbott ART, Roche CAP/CTM, and VERSANT HCV RNA 3.0 Assay (bDNA) were compared for all samples with paired quantitations within the reporting ranges of each pair of methods. Deming regression analysis demonstrated a linear relationship between the VERSANT kPCR and the comparator methods (Figure 2).

Conclusions

These results demonstrate quantitative equivalence and a linear relationship with no proportional bias between VERSANT HCV RNA 1.0 Assay (kPCR) and the comparator methods.

Reference