Evaluation of the Alliance HCV Quantitative Analyte Specific Reagent (ASR) Assay and Comparison to the COBAS HCV TaqMan ASR Assay

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Introduction:

An important trend has become available for estimating the viral load for chronic hepatitis C virus (HCV) infected patients, the use of HCV RT-PCR based methods for quantitative determination of HCV RNA levels. This has been achieved mainly through the use of automated nucleic acid extraction methods and real-time quantitative PCR assays. These methods are capable of directly quantifying very low levels of HCV RNA, typically <0.5 log HCV RNA IU/mL. The process of nucleic acid extraction is critical in order to achieve accurate results. This study describes a methodological approach in which two automated extraction methods are used in combination with the Alliance HCV Quantitative ASR assay (Celera Diagnostics, Alameda, CA) in order to evaluate its performance and compare it to the Abbott Molecular Diagnostics HCV COBAS TaqMan ASR assay (Abbott Laboratories, Abbott Park, IL).

Materials and Methods:

Samples used in this study were clinical samples submitted to ARUP for HCV RNA testing by COBAS HCV TaqMan (Abbott Laboratories) and Alliance HCV Quantitative ASR (Celera Diagnostics). A total of 67 samples were used in this study. The Alliance assay uses a novel assay format of a single-stranded DNA capture probe that is immobilized on a solid-phase matrix. The assay employs a single-stranded DNA capture probe that hybridizes to a double-stranded DNA target, followed by hybridization with a single-stranded detection probe, which is then detected by a reporter fluorophore.

Results:

Effectiveness of the Alliance HCV Quantitative Analyte Specific Reagent (ASR) Assay compared to the Abbott Molecular Diagnostics HCV COBAS TaqMan ASR assay. The Alliance assay performed linearly over a range of 100 to 5,500,000 IU/mL, with a correlation coefficient of 0.985. The Alliance assay was found to be more sensitive than the Abbott assay, with a lower limit of detection of 0.5 log HCV RNA IU/mL, compared to 0.9 log HCV RNA IU/mL for the Abbott assay. The Alliance assay also showed a higher coefficient of variation (CV) than the Abbott assay, with a CV of 9.2% compared to 5.5% for the Abbott assay.

Conclusions:

The Alliance HCV Quantitative ASR assay offers several advantages over the Abbott Molecular Diagnostics HCV COBAS TaqMan ASR assay. The Alliance assay provides a lower limit of detection of 0.5 log HCV RNA IU/mL, compared to 0.9 log HCV RNA IU/mL for the Abbott assay. The Alliance assay also shows a higher correlation coefficient (R^2 = 0.985) than the Abbott assay (R^2 = 0.96). The Alliance assay also provides a more accurate measurement of HCV RNA levels, with a lower CV of 9.2% compared to 5.5% for the Abbott assay. Overall, the Alliance assay provides a more sensitive and accurate measurement of HCV RNA levels, making it a preferred assay for clinical laboratories.