**BACKGROUND**

Determination of Hepatitis C Virus (HCV) RNA levels in plasma or serum is an important tool to characterize viral loads in infected patients to monitor disease progression, efficacy of antiviral therapies, as well as to detect drug resistant mutants and identify relapse upon discontinuation of antiviral therapy. The NeuMoDx HCV Test is an on-board molecular diagnostic assay incorporating a universal target isolation chemistry enabling extraction of HCV-specific RNA from serum and plasma specimens; combined with a sensitive and specific quantitative real-time PCR assay, all reagents and disposables are room temperature stable and can be stored at room temperature on the board-the system to provide a seamless, on-demand testing workflow.

**METHODS**

The NeuMoDx Molecular System automates and integrates the extraction, purification, quantification, and results interpretation of infectious disease nucleic acids targets using quantitative RT-PCR. The objective of this study was to test and report performance of the NeuMoDx HCV Test in key analytical performance metrics. Internal pre-analytical studies were performed to characterize the analytical sensitivity, linearity, precision, productivity, turnaround time, and results processing accuracy and are reported here.

**RESULTS**

The NeuMoDx HCV Test showed a detection limit and lower limit of quantification of 10 IU/mL, and demonstrated excellent linearity across a 6 Log dynamic range (1E-05 to 1E+05). Reproducibility and precision across multiple systems, operators, and reagent lots was also demonstrated. The NeuMoDx HCV Test also demonstrated excellent detection performance across all relevant HCV genotypes, with a Turnaround time (TAT) of ~75 min. The results processing module was upgraded for automated processing of data which provides accurate quantitative results, and excellent concordance was demonstrated in a method correlation study conducted between the NeuMoDx HCV Test and a reference test. An R² > 0.95 and bias of HCV viral load output from the two tests of less than 0.5 Log IU/mL, was obtained.

**HCV Analytical Sensitivity (LoD & LLoQ)**

The Limit of Detection of the NeuMoDx HCV Test was determined with pooled HCV-negative plasma spiked with Accuchek® HCV Control of known HCV spiked plasma using the Probit style analysis of the linear regression and the calculated LLLoQ was determined to be 10 IU/mL. The NeuMoDx HCV Test further demonstrated sensitivity by accurately detecting all eight relevant HCV genotypes across the LoD.

**Genotype Coverage**

The NeuMoDx HCV Test accurately detected all eight clinically relevant genotypes of HCV within LLLoQ of ~10 IU/mL. The Genotype Coverage Panel with 100% sensitivity and specificity was used to generate the linear regression and data from the study showed that the NeuMoDx HCV Test demonstrated excellent linearity across the 6 Log with a maximum deviation from a slightly better fitting non-linear regression of 0.5 Log, IU/mL.

**HCV Linearity**

The linearity of the NeuMoDx HCV Test was determined by dialyzing either Accuchek® HCV RNA or AmpliSens® HCV Amplicor RNA in pooled HCV-negative plasma to create a panel spanning eight log of HCV concentration ranging from 1 Log, IU/mL, to 100 Log, IU/mL. Data from this study showed that the NeuMoDx HCV Test demonstrated excellent linearity across the 6 Log with a maximum deviation from a slightly better fitting non-linear regression of 0.5 Log, IU/mL.

**Precision**

The Within Run Precision of the NeuMoDx HCV Test was determined by testing a 5 member panel of HCV on multiple NeuMoDx Molecular Systems across multiple runs. The means were characterized and the standard deviation for both was determined to be a 0.5 Log, IU/mL.

**Conclusion**

The NeuMoDx HCV Test is an extremely easy to use, rapid, automated molecular test for the sensitive and accurate viral load monitoring required for effective patient management of HCV infections.

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