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Poster Session V
Molecular and non-molecular diagnostics of viruses

QUANTITATIVE DETECTION OF HEPATITIS C VIRUS (HCV) ON THE VERIS PLATFORM

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OBJECTIVE: The Beckman Coulter VERIS platform is a fully-automated, moderate complexity, random-access, sample-to-answer system for the quantitative/qualitative analysis of molecular targets. The VERIS platform incorporates the extraction, purification, quantification, and results interpretation of infectious disease nucleic acid targets using the polymerase chain reaction.

The VERIS Hepatitis C Virus (HCV) assay is an in vitro nucleic acid test, combining reverse transcription and real-time polymerase chain reaction (RT-PCR) assay, for the quantitative determination of HCV RNA in human plasma samples. It is intended to be used in conjunction with clinical presentation and other laboratory markers as an aid in monitoring HCV viral load for the detection of virus reactivation and disease, as well as for the management of patient therapy.

The objective of this study was to test and report performance of the VERIS HCV assay in key analytical and clinical measures.

METHODS: Verification and clinical validation of the HCV assay were performed. Analytical sensitivity, linearity, precision, inclusivity, trueness, turnaround time and method comparison with the Abbott RealTime HCV Assay are reported here.

RESULTS: The VERIS HCV assay is quantitative in the range 12 IU/mL to 100,000,000 IU/mL. Evaluation of the limit of detection (LoD) based on Probit analysis indicates that the assay is able to detect 12 IU/mL (95% CI). A comparison study was conducted between the VERIS HCV Assay and the Abbott RealTime HCV Assay using split samples. Bias of HCV viral load output from the two assays was less than 0.5 Log IU/mL. Trueness across the entire measuring interval of the VERIS HCV Assay using standards traceable to the 4th HCV WHO standard, indicate the maximum bias of the assay is within 0.3 Log IU/mL of the nominal input. VERIS HCV Assay precision is within a total SD of 0.2 Log IU/mL. Turnaround time for the VERIS HCV Assay is less than <110 min. The assay is able to provide quantitative results from human plasma (K2EDTA) specimens containing HCV genotypes 1 through 6.

CONCLUSION: Based on these data, the VERIS HCV assay is a rapid, automated molecular test for the sensitive, repeatable, and accurate viral load monitoring required for effective patient management of HCV infection.