P1422
Poster Session V
Molecular and non-molecular diagnostics of viruses

QUANTITATIVE DETECTION OF HEPATITIS B VIRUS (HBV) 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 integrates the sample extraction, purification, and reaction setup with the detection, quantification, and results interpretation of infectious disease nucleic acid targets using the polymerase chain reaction. The initial VERIS assay menu includes the Hepatitis B Virus (HBV) assay for use in conjunction with clinical presentation and additional laboratory markers, to aid in monitoring HBV viral load for patient management.

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

METHODS: Verification and clinical validation of the HBV assay were performed. Analytical sensitivity, linearity, precision, inclusivity, trueness and method comparison with the COBAS AmpliPrep®/COBAS TaqMan® HBV Test from both plasma and serum are reported here.

RESULTS: The HBV assay provides quantitative results from 10 to 1.0 x 10^9 IU/mL for subgenotypes A1, A2, B2, B4, C2, D1, D3, E, F2, G, and genotype H. The VERIS HBV test reports precision within a total standard deviation of 0.2 log IU/mL and a <0.5 log IU/mL bias in results from the COBAS AmpliPrep®/COBAS TaqMan® HBV Test across a 9 log range.

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