P1405
Poster Session V
Molecular and non-molecular diagnostics of viruses

CYTOMEGALOVIRUS (CMV) VIRAL LOAD ASSAY FOR THE VERIS PLATFORM

A. Silvestro[1], H. Duan[1], S. Lim[1], J. Richards[1], J. O'Neil[1], **C. Howell**[2], N. Tusneem[1], E. Gustafson[1], T. Scholl[1]

[1]Molecular Diagnostics, Beckman Coulter, Danvers MA, USA ; [2]Molecular Diagnostics, Beckman Coulter, Brea CA, USA

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 initial VERIS assay menu includes the cytomegalovirus Viral Load assay intended for use in conjunction with clinical presentation and other laboratory markers as an aid in monitoring CMV viral load and for the detection of virus reactivation.

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

METHODS: Verification and clinical validation of the CMV assay were performed. Analytical sensitivity, linearity, precision, analytical specificity and method comparison with the COBAS AmpliPrep®/COBAS TaqMan® CMV Test from plasma are reported here.

RESULTS: The VERIS CMV has a verified LoD of 27 IU/mL, determined from the upper limit of the 95% CI at 95% detection rate of the CMV WHO Standard. In addition, the assay has demonstrated linearity between 159 IU/mL (2.20 Log IU/mL) to 13,400,000 IU/mL (7.13 Log IU/mL) using the WHO-traceable reference strain, AD-169. The assay has a precision of less than or equal to 0.15 Log IU/mL across the linear range, with an observed difference from expected of <0.05 Log IU/mL. In addition, the CMV assay demonstrated a mean bias in CMV viral load of -0.02 IU/mL (95%CI from -0.13 to 0.10) when compared to a predicate device within each assay's overlapping linear ranges. Finally, the CMV assay has a verified specificity of 100% (lower bound two-sided 95% CI of 98.8%) when tested with CMV antibody and DNA-free plasma samples.

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