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Abstract (poster session)

Comparison of an automated molecular diagnostic assay for the quantitative determination of cytomegalovirus (CMV)

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Objectives/Introduction: Viral load monitoring has emerged as a critical tool in the management of transplant patients with CMV. We evaluated the performance of a new CMV molecular assay using the new WHO International Standard, human plasma samples as well as analytical testing to determine the limit of detection (LOD), and the clinically relevant measuring interval for quantitative results. The assay is performed on a new Beckman Coulter (BEC) molecular diagnostics platform that achieves routine testing of molecular diagnostic assays from “sample to results” in a simple, intelligent design that provides random access testing flexibility. Methods: BEC utilized a proprietary extraction methodology incorporated into an in vitro nucleic acid amplification real-time polymerase chain reaction (RT-PCR) assay to quantify CMV deoxyribonucleic acid (DNA) in human plasma. The assay includes a process control to monitor both the extraction and PCR steps of the process. Testing was performed on 0.25 mL of human plasma from primary and transfer tubes with sample extraction, amplification and detection performed on the automated BEC molecular diagnostics platform (in development). Results: Using the WHO standard we determined the BEC CMV assay provided quantitative values within 0.3 log IU/ml of the expected value across the measuring range 175 IU/mL to 10,000,000 IU/mL, with a limit of detection of 60 IU/mL. Clinical samples were tested with result compared to another commercially available method. The BEC CMV assay demonstrated comparable results with an r-squared value of x and no results exceeding x log IU/ml. The BEC CMV assay demonstrated comparable results to commercially marketed competitor assays for CMV. Common interfering substances found in plasma did not affect the accuracy of the assay. Conclusions: The BEC CMV DNA quantification assay demonstrated performance consistent with our design expectations for an assay utilized in the management of CMV infected individuals and provided comparable clinical results when compared to other The assay was simple to perform on the BEC automated molecular diagnostic platform that provided efficient workflow for our studies.