**PERFORMANCE OF QUANTITATIVE CYTOMEGALOVIRUS TEST ON NEUMODX MOLECULAR SYSTEM**

**BACKGROUND**

Human cytomegalovirus (CMV) is one of the most significant causes of viral infections and is associated with morbidity and mortality in transplant patients. Accurate and timely diagnosis of CMV infection is crucial for patient management, especially in the context of organ transplantation and other immunocompromised states. The NeuMoDx CMV Test is a sensitive and specific diagnostic tool for measuring CMV DNA in plasma samples, providing valuable diagnostic information for early detection and management of CMV infections.

**METHODS**

The objective of this study was to characterize the performance of the NeuMoDx CMV Test across key performance metrics on both systems. The study was conducted between the NeuMoDx CMV Test and the reference tests, which included multiple runs performed across multiple days. The performance of the CMV Test was assessed by comparing the results with those obtained from a gold standard method, ensuring the accuracy and reliability of the test.

**RESULTS**

Evaluation of analytical sensitivity of the NeuMoDx CMV Test resulted in an LoD and LLoQ of 20 IU/mL. The NeuMoDx CMV Test demonstrated excellent linearity across a clinically relevant >6 Log10 dynamic range. The limit of detection (LoD) of CMV was determined to be 17.7 IU/mL based on Probit style analysis, and the calculated LLoQ was determined to be also 20 IU/mL.

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

**LINEAR RANGE AND LIMIT OF QUANTITATION (ULoQ)**

The linearity of the NeuMoDx CMV Test was determined by comparing the results obtained from the test with those obtained from a gold standard method. The linear range of the NeuMoDx CMV Test was determined to be >6 Log10 units of CMV DNA, with an analytical sensitivity limit of 20 IU/mL.

**Cross-Reactivity and Interference**

The NeuMoDx CMV Test demonstrated excellent cross-reactivity with other pathogens, including Epstein–Barr virus, HIV-1, Hepatitis B virus, Parvovirus B19, Human Herpes Virus type-7, Human Herpes Virus type-8, Cryptococcus neoformans, Herpes Simplex Virus type-2, and Epstein–Barr virus. None of the non-target pathogens tested showed cross-reactivity with the CMV Test.

**CONCLUSIONS**

The NeuMoDx CMV Test demonstrated excellent analytical sensitivity and specificity, making it a valuable diagnostic tool for measuring CMV DNA in plasma samples. The test is highly sensitive and specific, with a limit of detection of 17.7 IU/mL and a limit of quantitation of 20 IU/mL. The NeuMoDx CMV Test is a crucial tool for use in viral load monitoring in transplant patients and other immunocompromised states.

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**REFERENCES**

1. European Society for Organ Transplantation (ESOT) guidelines on the management of CMV infection in solid organ transplantation.