QUANTITATIVE DETECTION OF EPSTEIN-BARR VIRUS (EBV) IN PLASMA AND WHOLE BLOOD

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BACKGROUND

Immuno-compromised individuals lacking EBV antibodies, especially at risk for acute EBV infection that may cause significant mortality and morbidity in organ transplant recipients. Quantitative detection of EBV DNA can be critical in the diagnosis and management of such patients. The NeuMoDx EBV Test is a "sample to result" type in which a low volume of whole blood is aspirated, incorporating automated extraction of EBV DNA from whole blood and plasma specimens, combined with a sensitive real-time PCR assay to deliver highly accurate results in a completely automated manner.

METHODS

Performance of the NeuMoDx EBV Test was characterized in both plasma and whole blood matrices. The objective of this study was to test and report performance of the NeuMoDx EBV Test across various performance metrics. Studies were performed to characterize the analytical sensitivity, limits of quantitation, precision, extraction turnaround time, and equivalency across specimen types. Testing was performed using either a 200 µL sample of plasma or a 200 µL sample of whole blood matrix.

RESULTS

Evaluation of the analytical sensitivity using a Poisson style analysis was performed using the 1st WHO International EBV Standard. The limit of detection (LoD) was determined to be 18.8 IU/mL with a Linear LoQ (LLoQ) of 20.2 IU/mL.

PLASMA

The linearity of the NeuMoDx EBV Test was determined with spiked plasma. The NeuMoDx EBV Test demonstrated excellent linearity across plasma for concentrations ranging from 110 Log10 IU/mL to 5 Log10 IU/mL. The NeuMoDx EBV Test demonstrated excellent robust quantitation linearity across a wide dynamic range and performs well across multiple reagent lots and in multiple days.

WHOLE BLOOD

The linearity of the NeuMoDx EBV Test was determined with spiked whole blood. The NeuMoDx EBV Test demonstrates excellent linearity across whole blood for concentrations ranging from 2 Log10 IU/mL to 5 Log10 IU/mL. The NeuMoDx EBV Test demonstrates excellent robust quantitation linearity across a wide dynamic range and performs well across multiple reagent lots and in multiple days.

EBV PLASMA TO WHOLE BLOOD EQUIVALENCE

The equivalence of the NeuMoDx EBV Test between matrices, plasma and whole blood was evaluated by spiking KOBEST plasma and KOBEST whole blood with EBV DNA at equivalent amount of EBV DNA (1.04 Log10 IU/mL) using WHO International Standard. Levels were spiked into the linear range of the test. Specimens were then processed as the System. The NeuMoDx EBV Test demonstrated excellent correlation between plasma and whole blood matrices with Deming and Passing-Bablok line regression analyses.

CONCLUSIONS

The NeuMoDx EBV Test demonstrated excellent performance and is well suited for implementing viral load monitoring using both plasma and whole blood specimens.

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