The NeuMoDx EBV Assay demonstrated a limit of detection (LoD) and a lower limit of quantitation (LLoQ) of 75 IU/mL in plasma and of 250 IU/mL in whole blood. The NeuMoDx EBV Assay showed excellent linearity

QUANTITATIVE DETECTION OF EPSTEIN-BARR VIRUS (EBV) IN PLASMA AND WHOLE BLOOD SPECIMENS
Michelle Mastronardi*, Maureen Carey, Lijie Gong, Brad Keusch, Bilal Zgheib, Betty Wu, Sundu Brahmasandra, NeuMoDx Molecular, Ann Arbor, MI

BACKGROUND
The NeuMoDx EBV Assay is performed using a 1-step, semi-automated, selective real-time PCR assay to deliver highly accurate results in a completely automated manner. Performance of the NeuMoDx EBV Assay was characterized

METHODS
The objective of this study was to demonstrate performance of the NeuMoDx EBV Quant Assay in plasma and whole blood, as well as stability of NeuMoDx reagents. The NeuMoDx EBV Assay is a "sample to result" time PCR assay, delivered highly accurate results in a completely automated manner. Performance of the NeuMoDx EBV Assay was characterized in both plasma and whole blood on the NeuMoDx N96 and N288 Systems.

RESULTS
The NeuMoDx EBV Assay demonstrated a limit of detection (LoD) and a lower limit of quantitation (LLoQ) of 75 IU/mL in plasma and of 250 IU/mL in whole blood. These values were accepted as the Lower Limits of Quantitation (ULoQ) for both matrices.

NeuMoDx Molecular System Streamlined Testing

EBV Analytical Specificity (LoD & LLoQ)

EBV Linearity

LINEARITY AND UPPER LIMIT OF QUANTITATION (ULOQ)

Analytical Specificity & Interference

EXQUISIENCE BETWEEN PLASMA AND WHOLE BLOOD

AcroMetrix Equivalency Plot

AcroMetrix Equivalency Plot

Summary of linearity between NeuMoDx EBV Assay Calculated concentrations and manufacturer-supplied concentrations for a variety of viral analytes.

Drug Pools

Within Lab Precision

Lot-to-Lot Reproducibility

Performance Characterization

The NeuMoDx EBV Assay demonstrated excellent performance with both plasma and whole blood specimens as implemented on the NeuMoDx N96 and N288 Systems, molecular reagents for on-label monitoring.

CONCLUSIONS

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the help and support provided by all members of the NeuMoDx team. We would also like to thank our colleagues for their valuable assistance in reviewing, accessing, and editing this manuscript.