Performance of EBV QN assay from Altona Diagnostics

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Introduction

Epstein-Barr Virus (EBV) is a member of the family Herpesviridae. It has a double stranded 172 kbp DNA which exists in a linear form in the mature virion and in a circular, episomal form in latently infected cells. EBV primarily infects lymphoid cells of the B lineage. EBV is unique among the herpesviruses in its ability to transform precursor and mature human B lymphocytes, converting them into lymphoblastoid lines capable of continuous proliferation. EBV is the etiologic agent of infectious mononucleosis. Virtually everyone becomes infected with the virus at some time during life. Childhood infections are mostly asymptomatic. EBV has been associated with some cancers, including Burkitt’s lymphoma and nasopharyngeal carcinoma (NPC). The virus is also increasingly being recognized as an important viral agent in transplant recipients.

Materials and Methods

**Materials:** One hundred eighteen, previously tested (urine, plasma and body fluids) clinical samples were extracted using Abbott m2000sp protocol.

**Methods:** Method 1. Laboratory-developed test (LDT) EBV quantitation assay based on Qiagen ASR real time qPCR and Acrometric quantification standards run on Abbott m2000rt instrument. Method 2. RealStar® EBV qPCR Kit 1.0 assay based on quantitative real time PCR from Altona Diagnostics run on Roche LC480. Analytical sensitivity and LOD were determined by run dilutions of the AcroMatrix® EBV Panel from Life Technologies/ThermoFisher and Altona standards provided in RealStar® EBV kit.

Results

The RealStar® EBV qPCR method demonstrated 97% agreement with the LDT assay: 110/113 clinical samples were detected and 61/62 were not detected by each method. Of the 113 detectable samples, 3 were close to the limit of quantification (LOQ) for each assay and were not detected. All detectable samples (N=110) were within tolerance +/- 0.6 log. Correlation regression was (R2=0.888). Based on the Bland-Altman analysis, the mean difference (bias) between the two assays was -0.338, with 95% confidence intervals (-1.200 and 0.527). Analytical specificity was 100% when run against 43 different microbial and viral targets. RealStar® EBV assay had the following characteristics: LOQ = 500cpmL; linear range 500-10,000,000 cp/mL slope, -3.286; R 2 value=0.9982; PCR efficiency, 97%.

Conclusions

This study demonstrates that RealStar® EBV qPCR from Altona Diagnostics performs as well as our fully validated, in-house assay. The performance characteristics are suitable for clinical diagnosis and monitoring of the transplant patient population..

References

8. CLSI MM17 – Verification and Validation of Multiplex Nucleic Acid Assays.