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Diagnostic performance of kPCR PLX CMV, EBV and BKV DNA assays and correlation with WHO international standards

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Background:
Virus quantification is relevant for monitoring patients at risk for virus infections and reactivations and for initiation and monitoring of antiviral treatment. A large number of diagnostic assays for virus quantification are available and comparability of virus quantification between different assays could be facilitated by calibration to international standards. This study evaluated the diagnostic performance of the kPCR PLX™ CMV, EBV and BKV DNA (kPCR) assays and correlated the results to the respective WHO International Standards.

Material/methods:
Dilution panels of the 1st WHO International Standards for Human Cytomegalovirus, Epstein-Barr Virus and BKV (WHO standards) in whole blood (CMV, EBV) or plasma (BKV) were submitted to nucleic acid extraction with Versant™ kPCR Molecular systems SP followed by the respective kPCR assay. Linear regression analysis was performed and conversion/correction factors were calculated by dividing the theoretical values of the WHO standards by the geometric means of the observed values. Clinical specimens (whole blood in case of CMV and EBV, plasma in case of BKV) were tested in parallel with kPCR assays and R-gene™ assays, the latter following nucleic acid extraction with the MagNA Pure LC System. Bland-Altman analysis and linear regression analysis were performed.

Results:
Correlation between theoretical values of the WHO standards and the kPCR assay values was good (R^2 >0.92). The correction factors between the results obtained with the kPCR assays and the theoretical values of the WHO standards were 1.79 for CMV and 4.31 for EBV. The conversion factor between the results obtained with the kPCR BKV assay in copies/ml and the theoretical value of the WHO standard in IU/ml was 1.67.

The intra- and inter-assay variabilities of the kPCR assays were determined using dilution panels of the WHO standards in whole blood (CMV, EBV) or plasma (BKV). For intra-assay variability the

coefficients of variation (CVs) ranged from 0.67% to 4.15%. For inter-assay variability CVs ranged from 0.85% to 14.40%.

For qualitative results the kPCR assay demonstrated an agreement of 94.7% (71/75, kappa 0.89) with the R-gene assay for CMV, 97.8% (44/45, kappa 0.95) for EBV and 100% (27/27; kappa 1.0) for BKV.

The correlation of quantitative results of the kPCR and the R-gene assays was good (R^2= 0.786 for CMV, 0.724 for EBV, 0.880 for BKV). The differences in quantification were within +/- 1 $\log_{10}$ of the averaged $\log_{10}$ results for 25 of the 27 specimens (93%) for CMV, for 22 of the 28 specimens (78%) for EBV, for 23 of the 23 specimens (100%) for BKV. Calibration of results to the WHO standards did not increase this percentage.

Conclusions:
kPCR assay results showed good correlation with the WHO standards and with R-gene assay results. Calibration to the WHO standard did not improve comparability of quantitative results.