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# P0051 Clinical evaluation of a laboratory-developed (LDT) quantitative BK virus PCR assay using the cobas omni utility channel

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**Background:** Monitoring of patients after solid organ transplantation includes the detection of BK virus (urine or plasma) for the early diagnosis of severe BK virus (BK) reactivation. The open channel on **cobas®** 6800 System, the **cobas omni** Utility Channel (UC), automates laboratory-developed tests using user-designed oligonucleotides. This study evaluated the clinical performance of using a quantitative LDT assay based on published primer/probe sets on the UC.

**Materials/methods: cobas® omni** Optimisation Kit and LightCycler480 was used to adapt a BK-PCR Assay (Hassan et al 2016; targeting the early gene region expressing large T-Antigen) to the **cobas®** 6800. For the study the **cobas® omni** Utility Channel Tool v3.0, and the new quantification tool was used. Inter/Intra-run variability and limit of detection LOD (5 fold dilutions of the 1st WHO standard, n=24 repetitions per dilution) of the assay was determined using spiked BK negative EDTA-plasma and urine. Performance was further analysed using quality control (Instand, Germany) and clinical samples (urine, EDTA-plasma and serum). Results were compared to routine PCR workflow using a CE-labeled PCR test (Altona Diagnostics).

**Results:** The LOD for the LDT-BK-Assay on the **cobas®** 6800 was 6,7 IU/ml (no sig. difference between urine and plasma/serum) with a liner range from 33 IU/ml to $10^{10}$ IU/ml. Max divergence between 24 repetitions (at 5x LOD) in 16 runs (8 days) was 1,3 ct. All quality control panel specimens (Instand Germany n= 19) were correctly identified. 258 clinical samples (urine, plasma/serum) were tested. After discrepancy analysis, there were 138 BK concordant positive, 109 concordant negative, while 11 samples remained discrepant (all low positive). The sensitivity and specificity of the UC assay were 93% and 97% respectively. The quantitative analysis revealed a strong correlation (linear regression) between the CE-labeled assay and the new BK-LDT assay with $r^2$= 0,97 (n=123 urine) and $r^2$= 0,94 (n=135 plasma/serum).

**Conclusions: cobas omni** Utility Channel is a convenient solution to automate LDT workflow. Here we could demonstrate the clinical use of a new quantitative LDT-BK assay on the open channel of the **cobas®** 6800 for the detection and quantification of BK Virus in urine or plasma.