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Evaluation of the Luminex ARIES system for the detection and quantification of BK virus DNA in plasma samples from kidney transplant recipients

Tong Her¹, Ted Schutzbank^{*2}

¹*St. John Hospital and Medical Center*

²*St. John Hospital and Medical Center; Specialized Testing and Microbiology*

Background: BK virus (BKV) is found throughout the world. Most infections occur in early childhood with no known associated disease. BKV establishes a latent infection in the kidneys. Seroprevalence in adults is ~90%. Roughly 40% of renal allograft recipients shed BKV in the urine, either transiently or continuously over weeks to months. BKV Nephropathy is asymptomatic, and usually discovered due to increase in serum creatinine levels. Nearly 50% of renal transplant patients with BKV nephropathy experience a significant loss of function of the transplanted kidney. It is routine practice to screen renal transplant recipients regularly for BK viremia. In this study we compared the performance of BKV qPCR analyte specific reagents (ASR) by EliTech, and Luminex for measuring BKV viral load in plasma using the Roche Cobas® z480 instrument, and the Luminex ARIES® platform respectively.

Material/methods: BKV DNA qPCR testing on the Roche z480 used ELITech 20X MGB Alert® BK Virus Primers and 20X MGB Alert® BK Virus Probe ASR reagents. The 25 µL reaction consisted of 1X of the primers, probe, MGB Alert Hot Start Master and MGB Alert® BK Virus Internal Control. DNA extracted from 1.0 mL of plasma using the Roche MagNA Pure was eluted into 50 µL of elution buffer, 5 µL of which was added to the qPCR reaction. Thermocycling conditions were 1 cycle each of 50°C for 2 minutes, 93°C for 2 minutes, and 40 cycles of 93°C for 15 seconds, 56°C for 30 seconds, and 72°C for 30 seconds. Sample volume for the ARIES® platform was 200µL; the final elution volume post-extraction was 150 µL, 50µL of which was added to the reaction tube containing the BKV MultiCode primers and the reaction master mix (Ready Mix).

Results: A BKV DNA linearity panel (Acrometrix) was analyzed on both platforms. The ARIES® and Roche z480 gave very similar results demonstrating a lower limit of detection of 500 copies/mL for both platforms. A total of 36 patients previously tested on the z480, with results spanning the tests linear range, were tested on the ARIES®. The BKV DNA copy number correlation between the two methods was very good with an R² value of 0.95. The average difference in log copy number between the two methods was -0.31, indicating that the ARIES® method may have slightly greater analytical sensitivity.

Conclusions: BKV quantification results were closely matched between the two different methods. The workflow with the ARIES® System is greatly simplified by elimination of DNA extraction and most hands-on steps. The high degree of automation allows samples to be tested as they arrive. The possibility of amplicon contamination is significantly reduced with the ARIES® System by using a fully self-contained test cassette that is not open to the environment.