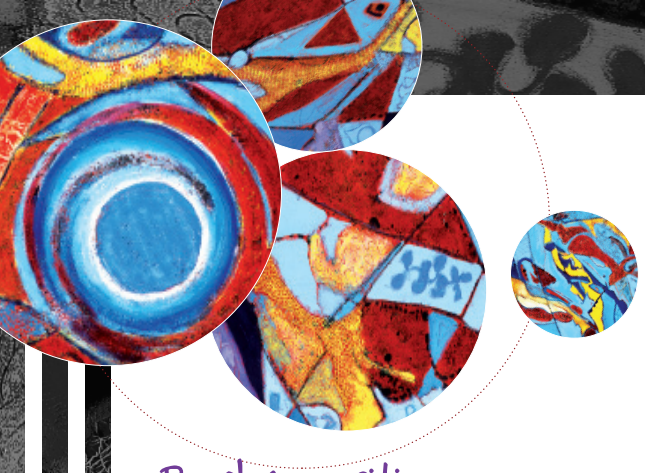

ARGENE

QCMD proficiency panels 2014

BK Virus

Panel composition

This EQA panel for the detection of BK Virus consisted of 8 samples containing various concentrations and strains of BKV, 1 JCV positive sample and 1 negative sample in transport medium (TM).

Material and methods

The QCMD panel was prepared using NucliSENS® easyMAG® (bioMérieux) for sample extraction with Specific B protocol (200/50).
Subsequently, the extracted samples were analysed by real-time PCR using **BK Virus R-gene®** (bioMérieux - ref.: 69-013B) on ABI 7500 Fast (Applied Biosystems).

Results and discussion

	QCMD Results				BK Virus R-gene® Results	
Panel code	Sample Content	Sample Type*	Copies/mL	Log_{10} Copies/mL	Log_{10} Copies/mL	Delta Log_{10} copies/mL
BKDNA14-01	BKV Ib-2 (TM)	Core	214	2.33	2.49	0.16
BKDNA14-02	BKV Ib-2 (TM)	Core	4,285	3.63	3.75	0.12
BKDNA14-03	BKV Ib-1 (TM)	Core	17,378	4.24	4.67	0.43
BKDNA14-04	BKV Ib-2 (TM)	Core	42,658	4.63	4.77	0.14
BKDNA14-05	BKV Ib-2 (TM)	Core	4,169	3.62	3.77	0.15
BKDNA14-06	JCV 1A (TM)	Core	Negative	NA	Negative	NA
BKDNA14-07	BKV Ib-2 / JCV 1A (VTM)	Educational	614	2.79	2.85	0.06
BKDNA14-08	BKV Ib-2 (VTM)	Core	1,057	3.02	3.00	-0.02
BKDNA14-09	Negative (TM)	Core	Negative	NA	Negative	NA
BKDNA14-10	BKV Ib-2 (VTM)	Educational	74	1.87	2.11	0.24

«The QCMD EQA panels contain a range of samples, designed to look at different aspects of assay performance. Panel members are designated 'core proficiency samples' on the basis of scientific information, clinical relevance and clinical experience (...). Laboratories are expected to correctly analyse and report the core proficiency samples in order to show acceptable proficiency.» QCMD 2014 general announcement
Consequently, the educational samples are considered as challenging due to very low concentrations. They are clearly detection limits.

- **The 6 Core BK Virus-positive samples from the BK Virus DNA EQA 2014 QCMD Panel are detected with BK Virus R-gene®.**
- **The 2 Core negative samples of BK Virus 2014 panel are undetected as expected with BK Virus R-gene®.**
- **The 2 Educational positive samples (i.e. challenging sample), containing a viral load of 614 copies/mL (BKVDNA14-07) and 74 copies/mL (BKVDNA14-10), are detected with BK Virus R-gene®.**
- **The delta log observed between QCMD and Argene quantification results (ranging from -0.02 to 0.43 Log_{10} copies/mL) are always below 0.5 log_{10}, showing the excellent correlation between both quantifications.**
- **The results show the good sensitivity and specificity of the BK Virus R-gene® (ref.: 69-013B)**

Sensitivity of BK Virus R-gene®

The analytical sensitivity of the kit has been determined on a range of dilution of BKV sample from Accrometrix panel, quantified at 5.10^3 copies/mL. Serial dilution were carrying out using plasma, urine or whole blood that has previously tested negative. The results obtained show :

- 95% probability of detecting BK Virus in plasma at 65 copies/mL
- 95% probability of detecting the BK Virus in urine at 140 copies/mL
- 95% probability of detecting the BK Virus on whole blood at 260 copies/mL

"The data presented in this document illustrates the performance of the BK Virus R-gene® assay when testing the BK Virus DNA EQA 2014 QCMD Panel. The results are not representative of the QCMD EQA program report and full details on the QCMD EQA program can be obtained from the QCMD website (www.qcmd.org)".

BIOMÉRIEUX

BK Virus R-gene®