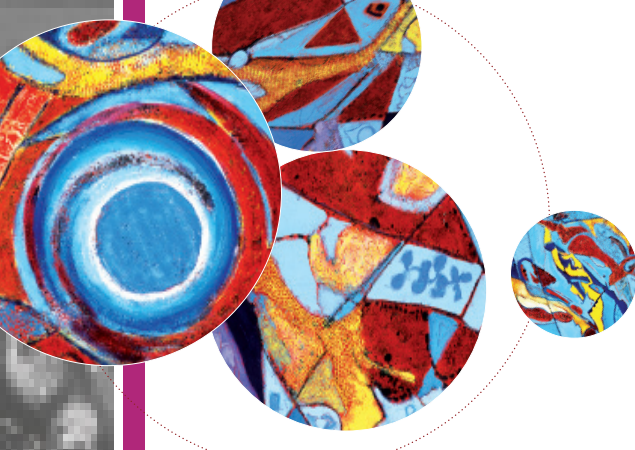


BK virus



Panel composition

This EQA panel for the detection of JC/BK consisted of 5 samples containing various concentrations and strains of BK, 6 samples containing various concentrations and strains of JC, 1 negative sample.

Material and methods

The QCMD panel was prepared using NucliSENS® easyMAG® (bioMérieux) for sample extraction with Specific B protocol (200/50).

Subsequently, the samples were analysed by real-time PCR using **BK Virus R-gene®** (bioMérieux - ref.: 69-013B) on Dx Real Time System (Bio-Rad).

Results and discussion

Panel code	Sample Content	QCMD Results			BK Virus R-gene® Results	
		Sample Type*	Copies/mL	Log ₁₀ Copies/mL	Log ₁₀ Copies/mL	Delta Log ₁₀ copies/mL
JC.BK13-01	BKV1b-1 (VTM)	Core (BKV)	508	2.71	2.77	0.06
JC.BK13-02	BKV1b-2 (VTM)	Core (BKV)	5,260	3.72	3.64	-0.08
JC.BK13-03	BKV1b-1 (VTM)	Core (BKV)	21,086	4.32	4.46	0.14
JC.BK13-04	JCV 1A (VTM)	Core (JCV)	16,596	4.22	Negative	NA
JC.BK13-05	JCV 1A (VTM)	Core (JCV)	2,109	3.32	Negative	NA
JC.BK13-06	BKV1b-2 (VTM)	Educational (BKV)	79	1.90	1.40	-0.50
JC.BK13-07	Negative (VTM)	Core	Negative	Negative	Negative	NA
JC.BK13-08	BKV1b-2 (VTM)	Core (BKV)	54,325	4.73	4.68	-0.05
JC.BK13-09	JCV 1A (VTM)	Educational (JCV)	314	2.53	Negative	NA
JC.BK13-10	JCV 2B (VTM)	Core (JCV)	1,122	3.05	Negative	NA
JC.BK13-11	JCV 3A (VTM)	Core (JCV)	535	2.73	Negative	NA
JC.BK13-12	JCV 3A (VTM)	Educational (JCV)	200	2.30	Negative	NA

*«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 2013 general announcement

Consequently, the educational samples are considered as challenging due to very low concentrations. They are clearly detection limits.

- The 4 "Core" BKV-positive samples of JC/BK 2013 QCMD Panel are detected with BK Virus R-gene®.
- The "Core" negative sample is undetected as expected with BK Virus R-gene®.
- The "Educational" BKV-positive sample (i.e. challenging sample), containing a viral load at 79 copies/mL is detected.
- All 6 JCV-positive samples are undetected as expected with BK Virus R-gene®.
- The delta log observed between QCMD and Argene quantification results (ranging from -0.50 to 0.14 Log₁₀ copies/mL) are always below 0.5 log₁₀, 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 5.10³ 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 JC/BK DNA EQA 2013 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)".