



BK VIRUS R-GENE®

REAL TIME PCR ASSAYS - ARGENE® TRANSPLANT RANGE

The power of true experience



PIONEERING DIAGNOSTICS



BK VIRUS R-GENE®

KEY FEATURES

- Ready-to-use reagents
- Complete qualitative and quantitative kit
- Validated on most relevant sample types
- Validated with the major extraction and amplification platforms
- Designed for low to high throughput analysis
- Same procedure for all the ARGENE® Transplant kits

CLINICAL CONTEXT^{1,2}

BK virus (BKV) is a DNA virus, member of the Polyomaviridae family. This is an ubiquitous virus with a seroprevalence reaching 90%. First infection, usually asymptomatic, most often occurs in early childhood. After primary infection, BKV migrates to the primary sites of latency, such as the kidney and the urothelium. During specific physiological or pathological states (e.g immunocompromised patients), BKV can be reactivated.

In transplant patients, BKV infection is linked to two major complications: BKV associated nephropathy in kidney transplant patients and BKV associated hemorrhagic cystitis in hematopoietic stem cell transplant patients^{1,2}.



TECHNICAL INFORMATION

ORDERING INFORMATION	BK Virus R-GENE® - Ref. 69-013B
Type of kit	Real-time detection and quantification kit
Gene target	Gene located in the Small T Antigen (StAg) area coding for StAg protein
Validated specimens	Whole blood, Plasma, Urine
Validated extraction platforms	EMAG®, easyMAG®, MagNA Pure Compact, MagNA Pure LC, MagNA Pure 96, QIA Symphony SP, QIAamp DNA Blood Mini Kit, DNA Extraction kit (ref. 67-000)
Validated amplification platforms	LightCycler 2.0, LightCycler 480 (System II), ABI 7500, ABI 7500 Fast, ABI 7500 Fast Dx, ViiA 7, StepOne, Rotor-Gene Q, CFX96
Limit of Detection (LoD 95%)	Whole Blood: 2.6 log ₁₀ copies/mL Plasma: 2.3 log ₁₀ copies/mL Urine: 2.5 log ₁₀ copies/mL
Quantification Range	Whole Blood: 2.6 to 8.4 log ₁₀ copies/mL Plasma: 2.3 to 9.0 log ₁₀ copies/mL Urine: 2.5 to 9.1 log ₁₀ copies/mL
Controls included	Extraction / Inhibition Control, Negative Control, Positive Control (QS3), 4 Quantification Standards, Sensitivity Control
Number of tests	90 tests
Storage conditions	-15°C / -31°C
Status	For <i>in vitro</i> diagnostic use, CE-IVD marking

OTHER ARGENE® TRANSPLANT KITS

- EBV R-GENE® (69-002B) • CMV R-GENE® (69-003B) • HSV1 HSV2 VZV R-GENE® (69-004B) • ADENOVIRUS R-GENE® (69-010B)
- Parvovirus B19 R-GENE® (69-019B) • CMV HHV6,7,8 R-GENE® (69-100B)

REFERENCES

1. Gilis et al. High burden of BK virus-associated hemorrhagic cystitis in patients undergoing allogeneic hematopoietic stem cell transplantation. *Bone Marrow Transplantation* 2014; 49: 664–670
2. Sueur et al. Toward Standardization of BK Virus Monitoring: Evaluation of the BK Virus R-gene Kit for Quantification of BK Viral Load in Urine, Whole-Blood, and Plasma Specimens. *J Clin Microbiol.* 2014; 52(12): 4298-304.