

Product specification affigene® BKV trender

Technical specification

Code No	71001084 (48 tests)
Intended use	Monitoring of BK virus (BKV) DNA in clinical samples
Regulatory status	CE labelled according to IVD Directive 98/79/EC for the complete process from sample preparation to result
Total kit size	48 determinations
Flexible run size	8-48 determinations per run (5-45 clinical samples)
Ready to use	All reagents provided in a ready-to-use format
Compatible profiles	Compatible profiles with other affigene® trender/ tracer assays enabling multitarget runs
Contamination prevention	UDG technology, Single-use reagents
Prev. of false neg. results	Internal Control introduced during sample preparation
Software provided	Results reported by the affigene® analysis software
Sample	Serum and whole blood
PCR instrument compatibility	Validated according to CE/IVD standards for: Mx3000P/3005P (Agilent/Stratagene) iCycler iQ/iQ5 (BioRad) Rotor-Gene 3000/6000 (Qiagen/Corbett Research) ABI 7300 (Applied Biosystems)
Sample preparation compatibility	Validated according to CE/IVD-standards for: affigene® DNA extraction (Cepheid AB) NucliSens easyMAG (bioMérieux)

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Performance characteristics

Dynamic range Serum: ~100-1x10⁸ copies/ml
Whole blood: ~ 500-1x10⁸ copies/ml

Limit of Detection (LOD) Using affigene® DNA extraction:
Serum 200µl protocol:
223 copies/ml (95% confidence interval: 131-573 copies/ml)
Whole blood 50 µl protocol:
898 copies/ml (95% confidence interval: 591-1705 copies/ml)

Using easyMAG:

Serum 500 µl protocol:
54 copies/ml (95% confidence interval: 35-112 copies/ml)
Whole blood 100 µl protocol:
464 copies/ml (95% confidence interval: 307-984 copies/ml)

Quantitative range Using affigene® DNA extraction:
Serum: 1000 - 1.0x10⁸ copies/ml
Whole blood: 2000 - 1.0x10⁸ copies/ml

Using easyMAG:
Serum: 150 - 1.0x10⁸ copies/ml
Whole blood: 1000 - 1.0x10⁸ copies/ml

Precision ≤ 0.15 log₁₀ throughout the quantitative range. Determined with different lots, different operators at different test occasions.

Exclusivity and Microorganism Interference No cross-reactivity with relevant pathogens: SV40, JCV, CMV, EBV, VZV, HSV-1, HSV-2, HHV-6, HHV-7, HHV-8, Adenovirus type 2, Candida albicans, Aspergillus niger, human DNA, bacterial or fungal DNA