HOLOGIC

Panther Fusion® BKV Quant Assay

On-demand BKV viral load testing in plasma and urine.[1]

A flexible approach for monitoring BKV infection **validated against clinically relevant samples types.**[1]

High performance, walkaway automation[1]

Performance	
LoD	Plasma: 43.1 IU/mL Urine 143.6 IU/mL (1st WHO International Standard)
LLoQ	Plasma: 79 IU/mL Urine: 162 IU/mL (1st WHO International Standard)
Linear range	Plasma: 1.90 log IU/mL to 9.00 log IU/mL Urine: 2.21 log IU/mL to 9.30 log IU/mL
Method correlation	High correlation against a comparator assay on retrospective and contrived plasma and urine specimens across the linear range of the assay

Assay reproducibility in urine	
Log IU/mL	**Urine total SD**
2.59	0.16
3.55	0.10
4.58	0.07

SD = standard deviation.

The high reproducibility of the assay provides confidence that results are accurate regardless of where they are performed.[1]

Take control of your BKV viral load testing[1]

Product design			
Intended use	BKV viral load monitoring	**Validated sample types**	Plasma and urine.
Technology	Real-time Polymerase Chain Reaction	**Quantitative**	Calibration curve valid for up to 60 days. Controls valid for up to 30 days.
Target region	VP2 gene	**Sample input volume**	Primary tube (EDTA, PPT): 1.2 mL plasma. Secondary tube: 700 µL plasma. Urine 2000 µL with automated dilution factor.

PANTHER FUSION® BKV Quant Assay

The Panther Fusion® BKV Quant assay on the Panther Fusion system combines assay performance with flexible automation for viral load monitoring.[1,2]

Sample-to-result within a single integrated instrument[1,2]

Key automation characteristics	
Random access	No more batching; load samples as they arrive in your laboratory.
Plasma primary tube processing	No need for aliquoting or manual sample transfer. Tube flexibility: PPT and EDTA tubes validated.
Urine processing	Validated for urine processing. Use pre-filled tubes for urine dilution, which are then loaded directly onto the Panther® system.
Flexible sample and reagent loading	Panther Fusion ready to use, single dose assay reagent cartridge. Primary tube processing with positive sample identification. Run multiple assays from a single specimen tube at the same time.
Consolidated calibration and controls	Panther Fusion assay calibration valid for up to 60 days. Panther Fusion controls valid for up to 30 days.
Rapid turnaround time with STAT result option	First results in 2.4 hours. STAT result option: ability to prioritise results.

Ordering information

Aptima® Transplant assay	Items	Quantity	Catalogue number
PANTHER FUSION® BKV Quant Assay	Panther Fusion BKV Quant Assay (8 Cartridges containing 12 tests each)	96 tests	PRD-07232
	Panther Fusion BKV Quant Calibrators	3 sets	PRD-07234
	Panther Fusion EBV-BKV Quant Controls	5 sets	PRD-07158
	Aptima Urine Specimen Transfer Tubes	100 tubes	105575

Validated sample types

✓ Plasma: EDTA, PPT
✓ Urine

RUN ON PANTHER® FUSION®

CE EC REP **Hologic BV, Da Vincilaan 5, 1930 Zaventem, Belgium EC REP information wherever applicable.**

References: 1. Panther Fusion BKV Quant Assay [package insert]. AW-26020-001. San Diego, CA: Hologic, Inc.;2022 **2.** Panther/Panther Fusion Operator's Manual - Instructions for Use. AW-26055-001 Rev 001.

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