

PRODUCT INFORMATION

Product SKU	BKVH102
Product Name	BKV High Run Control
Kit Lot Number	17080102
Source Material	Inactivated BKV Virus
Date of Expiration	2019-01
Base Matrix	True EDTA Plasma
Preservatives	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-20°C or below
Regulatory Status	CE-IVD
Traceability	1 st BKV International Standard (14/212)
Testing Platform	In-house BKV Assay

This is an unassayed control and does not have assigned analyte values. The end user is responsible for determining the value of the control. This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.


As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

Lot Number	Product Description	Testing Results	Quantity
17080102	BKV High Run Control	Pass (Comparison of target value against reference standard)	5 vials

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

APPROVAL

Quality Assurance	Date
	04 Oct 17