

PRODUCT INFORMATION

Product SKU	BKVP200
Product Name	BKV Verification Panel 1.4mL
Kit Lot Number	21071308
Source Material	Inactivated BKV
Date of Expiration	2023-06-30
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.4 mL
Storage Temperature	-20°C or Below
Regulatory Status	For In Vitro Diagnostic Use (IVD)
Traceability	1 st WHO International Standard (14/212)
Testing Platform	In-House BKV Assay

This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

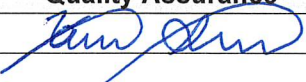
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation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

TESTING DATA

Lot Number	Product Description	Target Concentrations	Results
21071302	BKV Panel Member 1: 1E2 IU/mL 1.4mL	100 IU/mL	Pass
21071303	BKV Panel Member 2: 2E3 IU/mL 1.4mL	2,000 IU/mL	Pass
21071304	BKV Panel Member 3: 2E4 IU/mL 1.4mL	20,000 IU/mL	Pass
21071305	BKV Panel Member 4: 2E5 IU/mL 1.4mL	200,000 IU/mL	Pass
21071306	BKV Panel Member 5: 2E6 IU/mL 1.4mL	2,000,000 IU/mL	Pass
21071307	BKV Panel Member 6: 2E7 IU/mL 1.4mL	20,000,000 IU/mL	Pass

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

APPROVAL

Quality Assurance 	Date 27 Jul 21
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