

PRODUCT INFORMATION

Product SKU	BKVP100
Product Name	BKV Verification Panel
Kit Lot Number	20030407
Source Material	Inactivated BKV
Date of Expiration	2023-02-28
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-20°C or Below
Regulatory Status	CE-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 (cp/mL)	Target Concentrations (IU/mL)	Results
20030401	BKV Panel Member 1: 2E2 IU/mL	628 cp/mL	200 IU/mL	Pass
20030402	BKV Panel Member 2: 2E3 IU/mL	6,280 cp/mL	2,000 IU/mL	Pass
20030403	BKV Panel Member 3: 2E4 IU/mL	62,800 cp/mL	20,000 IU/mL	Pass
20030404	BKV Panel Member 4: 2E5 IU/mL	628,000 cp/mL	200,000 IU/mL	Pass
20030405	BKV Panel Member 5: 2E6 IU/mL	6,280,000 cp/mL	2,000,000 IU/mL	Pass
20030406	BKV Panel Member 6: 2E7 IU/mL	62,800,000 cp/mL	20,000,000 IU/mL	Pass

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

APPROVAL

Quality Assurance	Date
	28 Jun 20

Manufactured By: Exact Diagnostics, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107

For assistance and reordering, contact Exact Diagnostics at 817.989.9262

www.exactdiagnostics.com

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