

PRODUCT INFORMATION

Product SKU	HBVP200
Product Name	HBV Verification Panel 1.4mL
Kit Lot Number	21031808
Source Material	Inactivated HBV
Date of Expiration	2023-02-28
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	3 rd WHO International Standard (10/264)
Testing Platform	In-House HBV 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
21031801	HBV Panel Member 1: 1E2 IU/mL 1.4mL	100 IU/mL	Pass
21031802	HBV Panel Member 2: 1E3 IU/mL 1.4mL	1,000 IU/mL	Pass
21031803	HBV Panel Member 3: 1E4 IU/mL 1.4mL	10,000 IU/mL	Pass
21031804	HBV Panel Member 4: 1E5 IU/mL 1.4mL	100,000 IU/mL	Pass
21031805	HBV Panel Member 5: 1E6 IU/mL 1.4mL	1,000,000 IU/mL	Pass
21031806	HBV Panel Member 6: 1E7 IU/mL 1.4mL	10,000,000 IU/mL	Pass
21031807	HBV Panel Member 7: 1E8 IU/mL 1.4mL	100,000,000 IU/mL	Pass

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

APPROVAL

Quality Assurance	Date
	30Mar21