

PRODUCT INFORMATION

Product SKU	HBVP200
Product Name	HBV Verification Panel 1.4mL
Kit Lot Number	18042601
Source Material	Inactivated HBV
Date of Expiration	2020-04
Base Matrix	True EDTA Plasma
Preservatives	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.

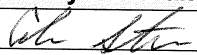
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation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

TESTING DATA

Lot Number	Product Description	Target Concentrations	Results
18042602	HBV Panel Member 1: 1E2 IU/mL 1.4mL	100 IU/mL	Pass
18042603	HBV Panel Member 2: 1E3 IU/mL 1.4mL	1,000 IU/mL	Pass
18042604	HBV Panel Member 3: 1E4 IU/mL 1.4mL	10,000 IU/mL	Pass
18042605	HBV Panel Member 4: 1E5 IU/mL 1.4mL	100,000 IU/mL	Pass
18042606	HBV Panel Member 5: 1E6 IU/mL 1.4mL	1,000,000 IU/mL	Pass
18042607	HBV Panel Member 6: 1E7 IU/mL 1.4mL	10,000,000 IU/mL	Pass
18042608	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
	13 Sep 18