

PRODUCT INFORMATION

Product SKU	HBVAMR
Product Name	HBV Analytical Measurement Range Panel
Kit Lot Number	18110276
Source Material	Inactivated HBV
Date of Expiration	2021-10-31
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.0 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.

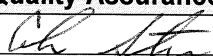
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation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

TESTING DATA

Lot Number	Product Description	Target Concentrations	Results
18110273	HBV AMR Panel Member 1: 1E2 IU/mL	100 IU/mL	Pass
18110274	HBV AMR Panel Member 2: 1E5 IU/mL	100,000 IU/mL	Pass
18110275	HBV AMR Panel Member 3: 1E7 IU/mL	10,000,000 IU/mL	Pass

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

APPROVAL

Quality Assurance	Date
	15 Nov 18