

PRODUCT INFORMATION

Product SKU	HBVH102
Product Name	HBV High Run Control
Kit Lot Number	22051202
Source Material	Inactivated HBV
Date of Manufacture	2022-05-16
Date of Expiration	2025-04-30
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-20°C or Below
Regulatory Status	CE-IVD
Traceability	3 rd WHO International Standard (10/264)
Testing Platform	In-House HBV Assay

This is an unassayed control and does not have assigned analyte values. The end user is responsible for determining the value of the control. 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 Concentration	Testing Results (Comparison of Target Value Against Reference Standard)	Quantity
22051202	HBV High Run Control	1,000,000 IU/mL	Pass	5 Vials

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

APPROVAL

Quality Assurance	Date
<i>Melody Hays</i>	<i>25 May 22</i>