

**PRODUCT INFORMATION**

<b>Product SKU</b>	HBVH102
<b>Product Name</b>	HBV High Run Control
<b>Kit Lot Number</b>	64567805
<b>Source Material</b>	Inactivated HBV
<b>Date of Manufacture</b>	2023-08-08
<b>Date of Expiration</b>	2026-07-31
<b>Base Matrix</b>	True EDTA Plasma
<b>Preservative</b>	ProClin® 300
<b>Fill Volume</b>	1.0 mL
<b>Storage Temperature</b>	-20°C or Below
<b>Regulatory Status</b>	CE-IVD
<b>Traceability</b>	3 <sup>rd</sup> WHO International Standard (10/264)
<b>Testing Platform</b>	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
64567805	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
	17 Aug 23