

**PRODUCT INFORMATION**

Product SKU	HBVH102
Product Name	HBV High Run Control
Kit Lot Number	19031101
Source Material	Inactivated HBV
Date of Expiration	2022-02-28
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
Traceability	3 <sup>rd</sup> 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
19031101	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
	11 Nov 20

Manufactured By: Exact Diagnostics, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107  
For assistance and reordering, contact Exact Diagnostics at 817.989.9262