

PRODUCT INFORMATION

Product SKU	HBVH102
Product Name	HBV High Run Control
Kit Lot Number	18030201
Source Material	Inactivated HBV
Date of Expiration	2020-02
Base Matrix	True EDTA Plasma
Preservatives	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-20°C or below
Regulatory Status	For In Vitro Diagnostic Use
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.

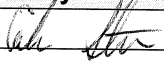
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation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

TESTING DATA

Lot Number	Product Description	Testing Results	Quantity
18030201	HBV High Run Control	Pass (Comparison of target value against reference standard)	5 vials

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

APPROVAL

Quality Assurance	Date
	04 Apr 18