

**PRODUCT INFORMATION**

<b>Product SKU</b>	HBVLOD
<b>Product Name</b>	HBV LOD
<b>Kit Lot Number</b>	18042701
<b>Source Material</b>	Inactivated HBV
<b>Date of Expiration</b>	2020-04
<b>Base Matrix</b>	True EDTA Plasma
<b>Preservatives</b>	ProClin® 300
<b>Fill Volume</b>	1.0 mL
<b>Storage Temperature</b>	-70°C or Below
<b>Regulatory Status</b>	For In Vitro Diagnostic Use
<b>Traceability</b>	3 <sup>rd</sup> WHO International Standard (10/264)
<b>Testing Platform</b>	Roche cobas® 6800/8800 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	Testing Results	Quantity
18042701	HBV LOD	Pass (≥ 95% detection rate)	10 Vials

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

**APPROVAL**

Quality Assurance	Date
	17 Sep 18