

**PRODUCT INFORMATION**

<b>Product SKU</b>	HIVH102
<b>Product Name</b>	HIV-1 High Run Control
<b>Kit Lot Number</b>	20012301
<b>Source Material</b>	Inactivated HIV-1
<b>Date of Expiration</b>	2022-12-31
<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>	For In Vitro Diagnostic Use
<b>Traceability</b>	3 <sup>rd</sup> WHO International Standard (10/152)
<b>Testing Platform</b>	In-House HIV-1 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
20012301	HIV-1 High Run Control	1,000,000 cp/mL	Pass	5 Vials

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

**APPROVAL**

<b>Quality Assurance</b>	<b>Date</b>
	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