

PRODUCT INFORMATION

Product SKU	HIVP200
Product Name	HIV-1 Verification Panel 1.4mL
Kit Lot Number	19062109
Source Material	Inactivated HIV
Date of Expiration	2021-05-31
Base Matrix	True EDTA Plasma
Preservative	ProClin® 300
Fill Volume	1.4 mL
Storage Temperature	-20°C or Below
Regulatory Status	For In Vitro Diagnostic Use
Traceability	3 rd WHO International Standard (10/152)
Testing Platform	In-House HIV-1 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	Target Concentrations	Results
19062102	HIV-1 Panel Member 1: 1E2 cp/mL 1.4mL	100 copies/mL	Pass
19062103	HIV-1 Panel Member 2: 6E2 cp/mL 1.4mL	600 copies/mL	Pass
19062104	HIV-1 Panel Member 3: 6E3 cp/mL 1.4mL	6,000 copies/mL	Pass
19062105	HIV-1 Panel Member 4: 6E4 cp/mL 1.4mL	60,000 copies/mL	Pass
19062106	HIV-1 Panel Member 5: 6E5 cp/mL 1.4mL	600,000 copies/mL	Pass
19062107	HIV-1 Panel Member 6: 2E6 cp/mL 1.4mL	2,000,000 copies/mL	Pass
19062108	HIV-1 Panel Member 7: 6E6 cp/mL 1.4mL	6,000,000 copies/mL	Pass

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

APPROVAL

Quality Assurance	Date
<i>Daylen Saper</i>	01/21/19

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

www.exactdiagnostics.com

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