

PRODUCT INFORMATION

Product SKU	HCVP200
Product Name	HCV Verification Panel 1.4mL
Kit Lot Number	21042101
Source Material	Recombinant HCV
Date of Expiration	2023-03-31
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	4 th WHO International Standard (06/102)
Testing Platform	In-House HCV 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
21042102	HCV Panel Member 1: 1E2 IU/mL 1.4mL	100 IU/mL	Pass
21042103	HCV Panel Member 2: 3E2 IU/mL 1.4mL	300 IU/mL	Pass
21042104	HCV Panel Member 3: 3E3 IU/mL 1.4mL	3,000 IU/mL	Pass
21042105	HCV Panel Member 4: 3E4 IU/mL 1.4mL	30,000 IU/mL	Pass
21042106	HCV Panel Member 5: 3E5 IU/mL 1.4mL	300,000 IU/mL	Pass
21042107	HCV Panel Member 6: 3E6 IU/mL 1.4mL	3,000,000 IU/mL	Pass
21042108	HCV Panel Member 7: 3E7 IU/mL 1.4mL	30,000,000 IU/mL	Pass

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

APPROVAL

Quality Assurance 	Date 04 May 21
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