

**PRODUCT INFORMATION**

<b>Product SKU</b>	HCVAMR
<b>Product Name</b>	HCV Analytical Measurement Range Panel
<b>Kit Lot Number</b>	19050911
<b>Source Material</b>	Recombinant HCV
<b>Date of Expiration</b>	2022-04-30
<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>	4 <sup>th</sup> WHO International Standard (06/102)
<b>Testing Platform</b>	In-House HCV Assay

This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

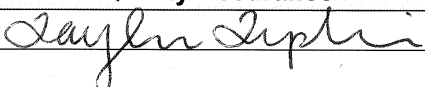
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation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

**TESTING DATA**

Lot Number	Product Description	Target Concentrations	Results
19050908	HCV AMR Panel Member 1: 5E2 IU/mL	500 IU/mL	Pass
19050909	HCV AMR Panel Member 2: 5E4 IU/mL	50,000 IU/mL	Pass
19050910	HCV AMR Panel Member 3: 5E6 IU/mL	5,000,000 IU/mL	Pass

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

**APPROVAL**

Quality Assurance	Date
	13 Jun 19