



CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System, in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485, European IVD Directive, the Canadian Medical Device Regulations (CMDR) and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® HCV Viral Load

Cepheid Catalogue Part No.: GXHCV-VL-CN-10

Kit Lot No.: 1001454053

Cartridge Lot No.: 39604

Kit Expiration Date: 2026-03-01

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Solna Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing according to D51112 Rev: E

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
LOW Positive	HCV DETECTED: 1.50-1.90 log ₁₀ IU/mL	Passed
HIGH Positive	HCV DETECTED: 4.25-4.55 log ₁₀ IU/mL	Passed
Negative	HCV NOT DETECTED	Passed

If checked this document is produced electronically and valid without a wet signature.

Signature of Quality Assurance,

2024 10 25

Date

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Title: QA Analyst