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 and the Canadian Medical Device Regulations (CMDR).

Product Name: Xpert® HCV Viral Load

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

Kit Lot No.: 1001457719

Cartridge Lot No.: 39704

Kit Expiration Date: 2026-02-15

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

Test Description	*Acceptance Criteria*	*Test Result*
LOW Positive	HCV DETECTED: 1.50-1.90 log10 IU/mL	Passed
HIGH Positive	HCV DETECTED: 4.25-4.55 log10 IU/mL	Passed
Negative	HCV NOT DETECTED	Passed

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

Samaneh Vahid 2024/12/0

Signature of Quality Assurance, **Date**

Name: Samaneh Vahid

Title: Senior QA Analyst