

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.:

1001472503

Cartridge Lot No.:

50402

Kit Expiration Date:

2026-07-26

Legal Manufacturer

Manufacturing Facility

Solna Sunnyvale

Cepheid AB Röntgenvägen 5

SE-17154 Solna

Sweden

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.

Signature of Quality Assurance,

Date

Name: Anton Andersson Engström

Title: QA Analyst