



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 Devices Regulations (CMDR).

Product Name: Xpert® HCV

Cepheid Catalogue Part No.: GXHCV-10

Kit Lot No.: 1001434794

Cartridge Lot No.: 10101

Kit Expiration Date: 2025-06-15

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden



Solna



Sunnyvale



Lodi

Functional Testing according to D70915, Rev. A

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|----------------------------|--------------------|
| Positive | HCV DETECTED | Passed |
| Negative | HCV NOT DETECTED | Passed |

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



Signature of Quality Assurance

20240711

Date

Name: Robert Fiedler

Title: QA Analyst