



## 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.:** 1001434796

**Cartridge Lot No.:** 10102

**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

2024 07 11

Date

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**Title:** QA Analyst