



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 VL Fingerstick

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

Kit Lot No.: 1000360753

Cartridge Lot No.: 13902

Kit Expiration Date: 2023-02-05

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Solna Sunnyvale Newark

Functional Testing according to Rev: G of: D27172

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
LOW Positive	HCV DETECTED: 2.29 - 2.67 log ₁₀ IU/mL	Passed
HIGH Positive	HCV DETECTED: 5.50 - 5.90 log ₁₀ IU/mL	Passed
Negative	HCV NOT DETECTED	Passed

Robert Fiedler

2022 02 20

Signature of Quality Assurance

Date

Name: Robert Fiedler

Title: QA Analyst