



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.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Solna Sunnyvale

Functional Testing according to DI4282 Rev.:

Test Description	Acceptance Criteria	Test Result
LOW Positive	HCV DETECTED: 1.50-1.90 log ₁₀ IU/mL	Passed
HIGH Positive	HCV DETECTED: 4.25-4.55 log ₁₀ IU/mL	Passed
Negative	HCV NOT DETECTED	Passed

Signature of Quality Assurance Date

Name:

Title: