



## 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<sup>®</sup> 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 D14282 Rev.:

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

Wafa 20220929

Signature of Quality Assurance

Date

Name:

Title: