Cepheid®

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.: GXHCV-VL-CE-10

Kit Lot No.: 1000207854

Cartridge Lot No.: 34002

Kit Expiration Date: 2021-07-11

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility ◉ Solna ○ Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing according to D14282 Rev.: L

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

Kambiz Ghaderi 20200731

Signature of Quality Assurance **Date**

Name: Kambiz Ghaderi

Title: QA Analyst