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.: 1000183794

Cartridge Lot No.: 33801

Kit Expiration Date: 2021-06-06

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.:* K

| *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 20200124

**Signature of Quality Assurance** **Date**

Name: Kambiz Ghaderi

Title: QA Analyst