



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.: 1000629613

Cartridge Lot No.: 36901

Kit Expiration Date: 2024-03-31

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: B of: D51112

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|---|--------------------|
| 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,

2022-12-23

Date

Name: Sara Mustafa Abdulla

Title: QA Analyst