



## 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.:** 1000421575

**Cartridge Lot No.:** 36502

**Kit Expiration Date:** 2023-10-01

**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: M of: D14282**

| <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             |

  
Signature of Quality Assurance,

Date

**Name:** Wafa Qasim

**Title:** QA Analyst