



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 Devices Regulations (CMDR).

Product Name: Xpert® HIV-1 Viral Load XC

Cepheid Catalogue Part No.: GXHIV-VL-XC-CE-10

Kit Lot No.: 1001447057

Cartridge Lot No.: 17102

Kit Expiration Date: 2026-03-15

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden



Solna



Sunnyvale



Lodi

Functional Testing according to D51111, Rev. C

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|---------------------------------------------------|--------------------|
| HIV-1 VL XC PC Low | HIV-1 DETECTED: 2.08-2.52 log ₁₀ IU/mL | Passed |
| HIV-1 VL XC PC High | HIV-1 DETECTED: 5.54-5.86 log ₁₀ IU/mL | Passed |
| Negative | HIV-1 NOT DETECTED | Passed |

If checked, this document is produced electronically and therefore valid without a wet signature


Signature of Quality Assurance

2024-09-26
Date

Name: Sara Mustafa Abdulla

Title: QA Analyst