



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 Qual XC

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

Kit Lot No.: 1001458509

Cartridge Lot No.: 14002

Kit Expiration Date: 2026-03-22

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility


Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Solna Sunnyvale

Functional Testing according to D36985 Rev: B

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|----------------------------|--------------------|
| HIV-1 Qual XC PC Low | HIV-1 DETECTED | Passed |
| Negative | HIV-1 NOT DETECTED | Passed |

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

 2024-11-22
Signature of Quality Assurance, Date

Name: Alexander Avramidis

Title: QA Analyst