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.: 1001457812

Cartridge Lot No.: 14307

Kit Expiration Date: 2026-05-10

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility ● Solna Sunnyvale
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing according to D36985 Rev: B

Test Description	*Acceptance Criteria*	*Test Result*
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.

Mustafa Didehvar
Mustafa Didehvar (Nov 26, 2024 13:48 GMT+1)

Signature of Quality Assurance, **Date**

Name: Mustafa Didehvar

Title: QA Analyst