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.: 1001443801

Cartridge Lot No.: 16705

Kit Expiration Date: 2026-02-22

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
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Sweden

Manufacturing Facility
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(●) Solna ( ) Sunnyvale ( ) Lodi

Functional Testing according to D51111, Rev. C

Test Description	*Acceptance Criteria*	*Test Result*
HIV-1 VL XC PC Low	HIV-1 DETECTED: 2.08-2.52 log10 IU/mL	Passed
HIV-1 VL XC PC High	HIV-1 DETECTED: 5.54-5.86 log10 IU/mL	Passed
Negative	HIV-1 NOT DETECTED	Passed

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

Robert Fiedler
Robert Fiedler (Nov 8, 2024 10:53 GMT+1)

Signature of Quality Assurance **Date**

Name: Robert Fiedler

Title: QA Analyst