

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.: 1001454055

Cartridge Lot No.: 17503

Kit Expiration Date: 2026-04-19

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
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● 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

Mustafa Didehvar
Mustafa Didehvar (Nov 4, 2024 12:13 GMT+1)
Signature of Quality Assurance

Date

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Title: QA Analyst