

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.: 1001462537

Cartridge Lot No.: 18007

Kit Expiration Date: 2026-06-07

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

Anton Engstrom

Anton Engstrom (Dec 19, 2024 09:17 GMT+1)

Signature of Quality Assurance

Date

Name: Anton Andersson Engström

Title: QA Analyst