



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, the Canadian Medical Devices Regulations (CMDR) and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® HIV-1 Viral Load

Cepheid Catalogue Part No.: GXHIV-VL-CN-10

Kit Lot No.: 1001467640

Cartridge Lot No.: 77503

Kit Expiration Date: 2026-02-15

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 D51110 Rev: D

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
LOW Positive	HIV-1 DETECTED: 2.07-2.53 log ₁₀ c/mL	Passed
HIGH Positive	HIV-1 DETECTED: 4.85-5.15 log ₁₀ c/mL	Passed
Negative	HIV-1 NOT DETECTED	Passed

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

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Signature of Quality Assurance

Date

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Title: QA Analyst