

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

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



Kit Lot No.: 1001448253

Cartridge Lot No.: 77408

Kit Expiration Date: 2025-11-30

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 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.

Cmf 20240930

Signature of Quality Assurance

Date

Name: Lava Maroof

Title: QA Analyst