



## 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.:** 1001421806

**Cartridge Lot No.:** 15207

**Kit Expiration Date:** 2025-09-14

**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. B**

| <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 <sub>10</sub> IU/mL | Passed             |
| HIV-1 VL XC PC High     | HIV-1 DETECTED: 5.54-5.86 log <sub>10</sub> IU/mL | Passed             |
| Negative                | HIV-1 NOT DETECTED                                | Passed             |

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

  
Signature of Quality Assurance

20240404  
Date

**Name:** Sara Mustafa Abdulla

**Title:** QA Analyst