



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 Device Regulations (CMDR).

Product Name: Xpert® HIV-1 Viral Load

Cepheid Catalogue Part No.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility

Solna Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

<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

 20190424

Signature of Quality Assurance

Date

Name:

Title: