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 Qual

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

Kit Lot No.: 1000178161

Cartridge Lot No.: 50201

Kit Expiration Date: 2021-04-25

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 according to D17328 Rev.: G

Test Description	*Acceptance Criteria*	*Test Result*
LOW Positive	HIV-1 DETECTED	Passed
HIGH Positive	HIV-1 DETECTED	Passed
Negative	HIV-1 NOT DETECTED	Passed

Kambiz Ghaderi 2019/2/05

Signature of Quality Assurance **Date**

Name: Kambiz Ghaderi

Title: QA Analyst