



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® HPV

Cepheid Catalogue Part No.: GXHPV-CE-10

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	HPV16 Positive, HPV18/45 Positive, other high risk HPV Positive	Passed
HIGH Positive	HPV16 Positive, HPV18/45 Positive, other high risk HPV Positive	Passed
Negative	HPV16 Negative, HPV18/45 Negative, other high risk HPV Negative	Passed

ROP

20210202

Signature of Quality Assurance

Date

Name:

Title: