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® HPV

Catalogue Part No.: GXHPV-CE-10

Kit Lot No.: 1001449412

Cartridge Lot No.: 30305

Kit Expiration Date: 2026-03-22

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
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

☐ If checked this document is produced electronically and valid without a wet signature.

2024-10-03

Signature of Quality Assurance **Date**

Name: Alexander Avramidis

Title: QA Analyst