



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.: 1001454939

Cartridge Lot No.: 30603

Kit Expiration Date: 2026-04-19

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility

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

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

Alexander Avramidis

Alexander Avramidis (Oct 30, 2024 13:36 GMT+1)

Signature of Quality Assurance

Date

Name: Alexander Avramidis

Title: QA Analyst