CERTIFICATE OF ANALYSIS

This certificate of analysis is provided to confirm that the device specified below meets 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, Regulation (EU) 2017/746 and the Canadian Medical Device Regulations (CMDR).

Product Name: Xpert® HPV v2

Cepheid Catalogue Part No.: GXHPV2-CE-10

Kit Lot No.: 1001456488

Cartridge Lot No.: 30901

Kit Expiration Date: 2026-05-10

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.

ROBERT FIEDLER 20241129

Signature of Quality Assurance **Date**

Name: Robert Fiedler

Title: QA Analyst