



## 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.:** 1001460185

**Cartridge Lot No.:** 30904

**Kit Expiration Date:**2026-05-17

**Legal Manufacturer**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna,  
Sweden

**Manufacturing Facility**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna,  
Sweden

***Functional Testing***

<b><i>Test Description</i></b>	<b><i>Acceptance Criteria</i></b>	<b><i>Test Result</i></b>
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

Robert Fiedler (Nov 27, 2024 11:56 GMT+1)

**Signature of Quality Assurance**

**Date**

**Name:** Robert Fiedler

**Title:** QA Analyst