



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.: 1001458928

Cartridge Lot No.: 30902

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

| <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.

Sara Mustafa Abdulla
Sara Mustafa Abdulla (Nov 29, 2024 07:34 GMT+1)

Signature of Quality Assurance

Date

Name: Sara Mustafa Abdulla

Title: QA Analyst