# 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 Device Regulations (CMDR).

Product Name: Xpert® HPV

Cepheid Catalogue Part No.: GXHPV-CE-10

Kit Lot No.: 1000180633

Cartridge Lot No.: 14103

Kit Expiration Date: 2021-04-18

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility (●) Solna ( ) Sunnyvale

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 |

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**Signature of Quality Assurance** **Date**

Name: Marie Bah

Title: QA Manager Release