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, the Canadian Medical Devices Regulations (CMDR), and the China National Medical Products Administration's Quality System Requirements.

Product Name: **Xpert® Xpress Flu/RSV**

Cepheid Catalogue Part No.: XPRSFLU/RSV-CE-10

Kit Lot No.: 1001504955

Cartridge Lot No.: 18001

Kit Expiration Date: 2027-11-07

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

(●) Solna ( ) Sunnyvale ( ) Lodi

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Negative	Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE	Passed
Low Positive	Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed
High Positive	Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed

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

William Palmén
William Palmén (11/24/2025 13:38:44 GMT+1)

11/24/2025

Signature of Quality Assurance, **Date**

Name: William Palmén

Title: QA Analyst