Cepheid

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 Devices Regulations.

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

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

Kit Lot No.: 1001412750

Cartridge Lot No.: 16501

Kit Expiration Date: 2025-12-07

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

(●) Solna ( ) Sunnyvale
( ) Newark ( ) 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.

Ron 20240205

Signature of Quality Assurance, **Date**

Name: Robert Fiedler

Title: QA Analyst