



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.: 1000692497

Cartridge Lot No.: 15505

Kit Expiration Date: 2025-01-12

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

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|--|--------------------|
| 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.

C. Maroof 2023-01-26
Signature of Quality Assurance, Date

Name: Lava Maroof

Title: QA Analyst