



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 CoV-2/Flu/RSV plus

Cepheid Catalogue Part No.: XP3COV2/FLU/RSV-10

Kit Lot No.: 1001454426

Cartridge Lot No.: 62923

Kit Expiration Date: 2025 10 19

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility


Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna Sunnyvale
 Newark Lodi IVD (B2)

Functional Testing

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|--|--------------------|
| Negative | SARS-CoV-2 NEGATIVE;Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE | Passed |
| Positive | SARS-CoV-2 POSITIVE;Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE | Passed |

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

 29 OCT 2024

Signature of Quality Assurance, Date

Name: Nhat Dao

Title: Quality Systems Specialist