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 CoV-2/Flu/RSV plus**

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

**Kit Lot No.:** 1000920348

**Cartridge Lot No.:** 26236

**Kit Expiration Date:** 2024-04-28

**Legal Manufacturer**

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

**Manufacturing Facility**

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

○ Solna ◉ Sunnyvale
○ Newark ○ Lodi IVD (B2)

***Functional Testing***

| *Test Description* | *Acceptance Criteria* | *Test Result* |
|---|---|---|
| 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.

Molly Doan 15May23

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

**Name:** Molly Doan

**Title:** Quality Systems Specialist