



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.: 1000375065

Cartridge Lot No.: 05621

Kit Expiration Date: 2023-01-08

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility


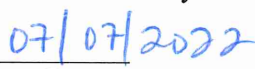
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

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 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.

 
Signature of Quality Assurance, Date

Name: Jenny Nguyen

Title: Quality Assurance Supervisor