

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 Adn IVD Directive and the Cana | ninistration's Quality System Requadian Devices Regulations. | uirements, ISO 1 | 3485, I | European | | |
|--|---|------------------|---------|-------------|--|--|
| Product Name: Xpert® Xpress CoV-2/Flu/RSV plus | | | | | | |
| Cepheid Catalogue Part | No.: XP3COV2/FLU/RSV- | 10 | | | | |
| Kit Lot No.: 1000454829 | | | | | | |
| Cartridge Lot No.: 08714 | | | | | | |
| Kit Expiration Date: 2023-07-09 | | | | | | |
| Legal Manufacturer | Manufacturing Facility | Solna | | innyvale | | |
| Cepheid | Cepheid | Newark | OLo | di IVD (B2) | | |
| 904 Caribbean Drive | 904 Caribbean Drive | | | | | |
| Sunnyvale, CA 94089 | Sunnyvale, CA 94089 | | | | | |
| USA | USA | | | | | |
| 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 | | |

| Negative | gative NEGATIVE;RSV NEGATIVE | | |
|---------------------|--|--------|--|
| Positive | SARS-CoV-2 POSITIVE;Flu A POSITIVE;Flu | Desaid | |
| Fositive | B POSITIVE;RSV POSITIVE | Passed | |
| If checked this doc | ument is produced electronically and valid without a wet signa | ture | |

Signature of Quality Assurance, Date Name: Molly Doan Title: Quality Systems Specialist