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.: 1000328101

Cartridge Lot No.: 02013

Kit Expiration Date: 2022-09-04

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ○ Solna ◉ Sunnyvale ○ Newark

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
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

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

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Signature of Quality Assurance, **Date**

Name: Emaela S. Quan-Tong

Title: Quality Assurance Supervisor