

## **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: Xpe	rt® Xpress CoV-2/Flu/RSV plus	
Cepheid Catalogue Part	No.: XP3COV2/FLU/RSV-10	
Kit Lot No.: 1000451506		
Cartridge Lot No.: 08711		
Kit Expiration Date: 202	3-07-02	
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Functional Testing		nnyvale di IVD (B2)
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	Passed

Test Description	Acceptance Criteria	1 est Resutt	
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, Name: Molly Doan Title: Quality Systems Specialist