

## **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

	ministration's Quality System Requadian Devices Regulations.	uirements, ISO 1	.3485, E	European	
Product Name: Xpe	ert® Xpress CoV-2/Flu/RSV plus				
Cepheid Catalogue Part	No.: XP3COV2/FLU/RSV-	10			
Kit Lot No.: 1000413387					
Cartridge Lot No.: 07122	2				
Kit Expiration Date: 2023-05-14					
Legal Manufacturer	Manufacturing Facility	OSolna (		nnyvale	
Cepheid	Cepheid	ONewark	Oro	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		

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 che	ecked this document is produced electronically and valid without a wet signature.
£.	equant 06JULDD
Signatu	re of Quality Assurance, Date
	Emaela S. Quan-Tong
Title:	Quality Assurance Supervisor