

## **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.

•	adian Devices Regulations.	European
Product Name: Xpert® Xpress CoV-2/Flu/RSV plus		
Cepheid Catalogue Part	No.: XP3COV2/FLU/RSV-10	
Kit Lot No.: 1001408269 Cartridge Lot No.: 1840		
Kit Expiration Date: 202	4-12-29	
Legal Manufacturer	Manufacturing Facility  Solna  Sunnyvale	
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Cepheid AB  Röntgenvägen 5  SE-171 54 Solna  Sweden	di IVD (B2)
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
1 1	t is produced electronically and valid without a wet signat  202410125  urance, Date	ure.
Title: QA Release Coor	dinator	