

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.

US Food and Drug Adm Directive and the Canad		s Quality System Require Regulations.	ements, ISO 13485, Euro	pean IVD
Product Name:	Xpert®	Xpress CoV-2 plus		
Cepheid Catalogue Par	t No.: X	XP3SARS-COV2-10		
Kit Lot No.: 10005	36837			
Cartridge Lot No.:	11524			
Kit Expiration Date: 2023-10-08				
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA		anufacturing Facility pheid AB ntgenvägen 5 -171 54 Solna reden	Solna Sunnyval	e Newark Lod
Functional Testing				
Test Description		Acceptance Criteria		Test Result
Negative	SARS-CoV-2 NEGATIVE		Passed	

SARS-CoV-2 POSITIVE

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

Signature of Quality Assurance,

Date

Name: Alexander Avramidis

Title: QA Analyst

Positive

Passed