

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.

Directive and the Canadian Devices Regulations.		
Product Name:	Xpert® Xpress CoV-2 plus	
Cepheid Catalogue Part	No.: XP3SARS-COV2-10	
Kit Lot No.: 100143	38104	
Cartridge Lot No.:	16002	
Kit Expiration Date: 2025-07-06		
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 US	Manufacturing Facility Cepheid AB Röntgenvägen 5 A SE-171 54 Solna Sweden	e Newark OLodi
Functional Testing		
Test Description	Acceptance Criteria	Test Result
Negative	SARS-CoV-2 NEGATIVE	Passed
Positive	SARS-CoV-2 POSITIVE	Passed

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

Signature of Quality Assurance,

Date

Name: Robert Fiedler

Title: QA Analyst