



## 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 Medical Device Regulations (CMDR).

Product Name: Xpert Xpress SARS-CoV-2

Cepheid Catalogue Part No.: XPRSARS-COV2-10

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Manufacturing Facility    Solna    Sunnyvale    Newark

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

*Functional Testing*

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
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

12/19/2022  
Date

Name:

Title: