Cepheid

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.: 1000552279

Cartridge Lot No.: 09107

Kit Expiration Date: 2023-09-10

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

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.

Molly Doan 01Nov22

Signature of Quality Assurance **Date**

Name: Molly Doan

Title: Quality Systems Specialist