

## 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.

**Product Name:** Xpert<sup>®</sup> Xpress CoV-2 *plus*

**Cepheid Catalogue Part No.:** XP3SARS-COV2-10

**Kit Lot No.:** 1001454042

**Cartridge Lot No.:** 16706

**Kit Expiration Date:** 2025-10-19

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

**Manufacturing Facility**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

Solna  Sunnyvale  Newark  Lodi

***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.

Robert Fiedler

Robert Fiedler (Nov 4, 2024 11:09 GMT+1)

**Signature of Quality Assurance,**

**Date**

**Name:** Robert Fiedler

**Title:** QA Analyst