



## 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 and ISO 13485.

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

**Instructions for Use (IFU)**

**Catalogue Part No.:** XPRS-COV2-10

**Part No. and Rev.:**

302-8997 Rev. B

**Kit Lot No.:** 1001453872

**Cartridge Lot No.:** 20904

**Kit Expiration Date:** 2025 10 19

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA  
94089 USA

**Manufacturing Facility**

Cepheid  
121 N Guild Avenue  
Lodi, CA 95240  
USA

Solna  
 Lodi

Sunnyvale

***Functional Testing according to D48538, Rev. J***

| <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,**

\_\_\_\_\_  
**Date**

**Name:** Crystal Sysenglath

**Title:** Quality Systems Specialist