



## 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® Xpress CoV-2 *plus*

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

**Kit Lot No.:** 1001223366

**Cartridge Lot No.:** 04736

**Kit Expiration Date:** 2024-09-15

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

**Manufacturing Facility**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

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.

Tanja Reed

Tanja Reed (Dec 13, 2023 10:01 PST)

Dec 13, 2023

**Signature of Quality Assurance,**

**Date**

**Name:** Tanja Reed

**Title:** Quality Systems Specialist





# 1001223366

Final Audit Report

2023-12-13

Created:	2023-12-13
By:	Tanja Reed (tanja.reed@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA3mh2D08RZsrQt08fHt1Ako4U3-hdWyPs

## "1001223366" History

-  Document created by Tanja Reed (tanja.reed@cepheid.com)  
2023-12-13 - 6:01:01 PM GMT
-  Document emailed to Tanja Reed (tanja.reed@cepheid.com) for signature  
2023-12-13 - 6:01:30 PM GMT
-  Document e-signed by Tanja Reed (tanja.reed@cepheid.com)  
Signature Date: 2023-12-13 - 6:01:40 PM GMT - Time Source: server
-  Agreement completed.  
2023-12-13 - 6:01:40 PM GMT