



## 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 Devices Regulations (CMDR).

**Product Name:** Xpert® CT/NG

**Cepheid Catalogue Part No.:** GXCT/NG-10

**Kit Lot No.:** 1001465328

**Cartridge Lot No.:** 43112

**Kit Expiration Date:** 2026 12 27

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94809 USA

**Manufacturing Facility**

Cepheid  
121 N Guild Avenue  
Lodi, CA 95240  
USA

Solna

Sunnyvale

Lodi

***Functional Testing according to D16904, Rev. AL.1***

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

01/22/25

Signature of Quality Assurance,

Date

**Name:** Asia Taylor Torres

**Title:** Quality Assurance Specialist



**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® Xpress CoV-2 plus

Instructions for Use (IFU)  
Part No. and Rev.:

Catalogue Part No.: XPRS-COV2-10

Kit Lot No.: 1001463886

Cartridge Lot No.: 21111

Kit Expiration Date: 2025 12 28

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. K*

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.

01/22/25

Signature of Quality Assurance, \_\_\_\_\_  
Date

Name: Asia Taylor Torres

Title: Quality Assurance Specialist