



## 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/Flu/RSV plus

**Cepheid Catalogue Part No.:** XP3COV2/FLU/RSV-10

**Kit Lot No.:** 1001405348

**Cartridge Lot No.:** 41006

**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 IVD (B2)

***Functional Testing***

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	SARS-CoV-2 NEGATIVE;Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE	Passed
Positive	SARS-CoV-2 POSITIVE;Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed

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

Tanja Reed  
Tanja Reed (Dec 22, 2023 08:15 PST)

Dec 22, 2023

**Signature of Quality Assurance,                      Date**

**Name:** Tanja Reed

**Title:** Quality Systems Specialist





# 1001405348

Final Audit Report

2023-12-22

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