



## **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, the Canadian Medical Devices Regulations (CMDR), and the China National Medical Products Administration's Quality System Requirements.

**Product Name:** Xpert® Xpress Flu/RSV

**Cepheid Catalogue Part No.:** XPRSFLU/RSV-CE-10

**Kit Lot No.:** 1001495368

**Cartridge Lot No.:** 17604

**Kit Expiration Date:** 2027-06-13

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

**Manufacturing Facility**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

☒ Solna


☐ Sunnyvale

☐ Lodi

***Functional Testing***

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE	Passed
Low Positive	Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed
High Positive	Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed

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

 2025-08-11  
**Signature of Quality Assurance,                      Date**

**Name:** Alexander Avramidis

**Title:** QA Analyst