



## 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® Xpress Flu/RSV**

Cepheid Catalogue Part No.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Solna

Sunnyvale

*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

3/28/2020

Signature of Quality Assurance

Date

Name:

Title: