



**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

Solna  Sunnyvale

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

*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             |

   
Signature of Quality Assurance Date

Name:

Title: