# 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.: XPRSFLU/RSV-CE-10

Kit Lot No.: 1000177438

Cartridge Lot No.: 12112

Kit Expiration Date: 2021-03-21

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility (•) Solna ( ) Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

*Functional Testing*

| *Test Description* | *Acceptance Criteria* | *Test Result* |
|---|---|---|
| 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 |

S Vahid 20191127

**Signature of Quality Assurance** **Date**

Name: Samaneh Vahid

Title: QA Analyst