Cepheid®

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.: 1000147067

Cartridge Lot No.: 10708

Kit Expiration Date: 2020-07-05

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

20190305

Signature of Quality Assurance **Date**

Name: Marie Bah

Title: QA Manager Release