



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

Catalogue Part No.: XPRSFLU-10

Kit Lot No.: 1001450322

Cartridge Lot No.: 46603

Kit Expiration Date: 2026-08-23

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	Passed
Low Positive	Flu A POSITIVE;Flu B POSITIVE	Passed
High Positive	Flu A POSITIVE;Flu B POSITIVE	Passed

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

ThuyTien Nguyen
ThuyTien Nguyen (Sep 27, 2024 15:27 PDT)

Sep 27, 2024

Signature of Quality Assurance

Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





1001450322

Final Audit Report

2024-09-27

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