



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 and ISO 13485.

Product Name: Xpert® Xpress MVP

Cepheid Catalogue Part No.: XPRSMVP-10

Kit Lot No.: 1001468098

Cartridge Lot No.: 03401

Kit Expiration Date: 2025 11 02

Legal Manufacturer

Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid 121 N Guild Avenue Lodi, CA 95240 USA

Solna

Sunnyvale

Lodi

Functional Testing according to D36990, Rev. E.1

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	BV POSITIVE; Candida group DETECTED; Candida glab-krus DETECTED; TV DETECTED	Passed
Negative	BV NEGATIVE; Candida group NOT DETECTED; Candida glab-krus NOT DETECTED; TV NOT DETECTED	Passed

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

ACT

01/13/25

Signature of Quality Assurance

Date

Name: Asia Taylor Torres

Title: Quality Assurance Specialist