



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.: 1001467155

Cartridge Lot No.: 03302

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


Signature of Quality Assurance 01/09/2025 Date

Name: James Moua

Title: Quality Systems Specialist