



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.: 1001464475

Cartridge Lot No.: 03103

Kit Expiration Date: 2025 10 12

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

12/20/2024

Signature of Quality Assurance

Date

Name: Mark Magno Shelor

Title: Quality Assurance Specialist