



## 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.:** 1001448205

**Cartridge Lot No.:** 02901

**Kit Expiration Date:** 2025-07-27

**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

 10/11/2024  
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**Signature of Quality Assurance** **Date**

**Name:** Mai Kue

**Title:** Quality System Specialists