



## 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.:** 1001450444

**Cartridge Lot No.:** 02808

**Kit Expiration Date:** 2025-06-01

**Legal Manufacturer**

Cepheid 904 Caribbean  
Drive Sunnyvale, CA 94089  
USA

**Manufacturing Facility**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
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

Molly Doan  
Molly Doan (Sep 30, 2024 14:33 PDT)

Sep 30, 2024

**Signature of Quality Assurance**

**Date**

**Name:** Molly Doan

**Title:** Quality Systems Specialist





# 302-8482 Rev B\_ C of A XPRSMVP

Final Audit Report

2024-09-30

Created:	2024-09-30
By:	Molly Doan (molly.doan@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA3NQRGKeAlhL0E6gfNGmpmGzggNcXTtoA6

## "302-8482 Rev B\_ C of A XPRSMVP" History

-  Document created by Molly Doan (molly.doan@cepheid.com)  
2024-09-30 - 9:32:17 PM GMT- IP address: 45.62.187.255
-  Document emailed to Molly Doan (molly.doan@cepheid.com) for signature  
2024-09-30 - 9:32:55 PM GMT
-  Document e-signed by Molly Doan (molly.doan@cepheid.com)  
Signature Date: 2024-09-30 - 9:33:02 PM GMT - Time Source: server- IP address: 45.62.187.255
-  Agreement completed.  
2024-09-30 - 9:33:02 PM GMT