

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.: XPRSMVI	P-10			
Kit Lot No.: 1001465325				
Cartridge Lot No.: 03303				
Kit Expiration Date: 2025-11-02				
Legal Manufacturer	Manufacturing Facility			
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089	Cepheid 121 N Guild Avenue		Solna	Sunnyvale
USA	Lodi, CA 95240 USA	• I	Lodi	

Functional Testing according to D36990, Rev.

Test Description	Acceptance Criteria	Test Result	
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

Pate

Name: Trinh Nguyen

Title: Quality Systems Specialist