



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® Mpox

Cepheid Catalogue Part No.: GXMPX-10

Kit Lot No.: 1001449336

Cartridge Lot No.: 01502

Kit Expiration Date: 2025-10-26

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 D61298, Rev. E

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MPXV Clade II Detected	Passed
Negative	MPXV Clade II Not Detected; OPXV Not Detected	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

ThuyTien Nguyen
ThuyTien Nguyen (Nov 9, 2024 10:03 PST)
Signature of Quality Assurance

Nov 9, 2024
Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





GXMPX-10 1001449336

Final Audit Report

2024-11-09

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