



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.: 1001449335

Cartridge Lot No.: 01501

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

Tann Tran
Tann Tran (Nov 6, 2024 22:36 PST)

Nov 6, 2024

Signature of Quality Assurance

Date

Name: Tann Tran

Title: Quality Systems Specialist





302-9627 Rev C_ C of A Xpert Mpox_1001449335

Final Audit Report

2024-11-07

| | |
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