



## 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.:** 1001449334

**Cartridge Lot No.:** 01406

**Kit Expiration Date:** 2025-10-12

**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. D**

| <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

Molly Doan  
Molly Doan (Oct 21, 2024 14:00 PDT)

Oct 21, 2024

**Signature of Quality Assurance**

**Date**

**Name:** Molly Doan

**Title:** Quality Systems Specialist





# 302-9627 Rev C\_ C of A Xpert Mpox (3)

Final Audit Report

2024-10-21

|                 |  |
|-----------------|--|
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