



## 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.:** 1001453680

**Cartridge Lot No.:** 01404

**Kit Expiration Date:** 2025-10-05

**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

Tann Tran  
Tann Tran (Oct 17, 2024 22:21 PDT)

Oct 17, 2024

**Signature of Quality Assurance**

**Date**

**Name:** Tann Tran

**Title:** Quality Systems Specialist





# 302-9627 Rev C\_ C of A Xpert Mpox 1001453680

Final Audit Report

2024-10-18

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