



## 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, ISO 13485, European IVD Directive and the Canadian Medical Devices Regulations (CMDR).

**Product Name:** Xpert<sup>®</sup> MTB/XDR

**Catalogue Part No.:** GXMTB/XDR-10

**Kit Lot No.:** 1001471404

**Cartridge Lot No.:** 04505

**Kit Expiration Date:**2026-07-12

**Legal Manufacturer**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna,  
Sweden

**Manufacturing Facility**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA



***Functional Testing***

<b><i>Test Description</i></b>	<b><i>Acceptance Criteria</i></b>	<b><i>Test Result</i></b>
Negative	MTB NOT DETECTED	Passed
Positive - Wild Type	MTB DETECTED;INH Resistance NOT DETECTED;FLQ Resistance NOT DETECTED;AMK Resistance NOT DETECTED;KAN Resistance NOT DETECTED;CAP Resistance NOT DETECTED;ETH Resistance NOT DETECTED	Passed
Positive - Mutant	MTB DETECTED;INH Resistance DETECTED;FLQ Resistance DETECTED;AMK Resistance DETECTED;KAN Resistance DETECTED;CAP Resistance DETECTED;ETH Resistance DETECTED	Passed

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

ThuyTien Nguyen  
ThuyTien Nguyen (Feb 7, 2025 10:40 PST)

Feb 7, 2025

**Signature of Quality Assurance**

**Date**

**Name:** ThuyTien Nguyen

**Title:** Quality Systems Specialist





# GXMTBXDR-10 1001471404

Final Audit Report

2025-02-07

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