



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[®] MTB/XDR

Catalogue Part No.: GXMTB/XDR-10

Kit Lot No.: 1001460360

Cartridge Lot No.: 04504

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

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
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 (Dec 13, 2024 15:23 PST)

Dec 13, 2024

Signature of Quality Assurance

Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist




GXMTB-XDR-10 1001460360

Final Audit Report

2024-12-13

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