Cepheid®

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 Device Regulations (CMDR).

Product Name: **Xpert MTB/XDR**

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

Kit Lot No.: 1001409456

Cartridge Lot No.: 03806

Kit Expiration Date: 2025-10-05

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility ○ Solna ◉ Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
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

01/16/2024

Signature of Quality Assurance **Date**

Name: ThuyTien Nguyen

Title: Quality Systems Specialist