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.: 1001462962

Cartridge Lot No.: 10501

Kit Expiration Date: 2026-09-06

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

(●) Solna ( ) Sunnyvale

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

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

2024-12-12

Signature of Quality Assurance **Date**

Name: Alexander Avramidis

Title: QA Analyst