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 Japanese Pharmaceuticals and Medical Devices Law, ISO 13485 and the European IVD Directive.

Product Name: Xpert® MTB/RIF

Cepheid Catalogue Part No.: GXMTB/RIF-JP-10

Kit Lot No.: 1001463772

Cartridge Lot No.: 94611

Kit Expiration Date: 2026-12-06

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Functional Testing according to D66612, Rev. A

Test Description	*Acceptance Criteria*	*Test Result*
Mutant Strain 1-High concentration ((MS1(H))	MTB DETECTED; Rif Resistance DETECTED	Passed
Mutant Strain 1-Low concentration ((MS1(L))	MTB DETECTED; Rif Resistance DETECTED	Passed
Mutant Strain 2-High concentration ((MS2(H))	MTB DETECTED; Rif Resistance DETECTED	Passed
Mutant Strain 2-Low concentration ((MS2(L))	MTB DETECTED; Rif Resistance DETECTED	Passed
Wild Type (WT) TB	MTB DETECTED; Rif Resistance NOT DETECTED	Passed
Negative Control	MTB NOT DETECTED	Passed

Final Judgement

Product Specification	*Judgement*
Sensitivity	Passed
Precision	Passed
Simultaneous Repeatability	Passed

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

2025-01-10
Signature of Quality Assurance, Date

Name: Alexander Avramidis

Title: QA Analyst