



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, the Canadian Medical Devices Regulations (CMDR) and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® MTB/RIF

Catalogue Part No.: GXMTB/RIF-CN-50

Kit Lot No.: 1001456978

Cartridge Lot No.: 94401

Kit Expiration Date: 2026-10-11

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden


Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MTB DETECTED VERY LOW; Rif Resistance NOT DETECTED or MTB DETECTED LOW; Rif Resistance NOT DETECTED or MTB DETECTED MEDIUM; Rif Resistance NOT DETECTED or MTB DETECTED HIGH; Rif Resistance NOT DETECTED	Passed
Negative	MTB NOT DETECTED	Passed

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

 2024-11-14

Signature of Quality Assurance **Date**

Name: Alexander Avramidis

Title: QA Analyst

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