

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 Ultra

Cepheid Catalogue Part No.: GXMTB/RIF-ULTRA-50

Kit Lot No.: 1001460214

Cartridge Lot No.: 73912

Kit Expiration Date: 2026-05-31

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB	Solna	Sunnyvale
Röntgenvägen 5		
SE-171 54 Solna		
Sweden	Lodi	

Functional Testing according to D25862, Rev. AN

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Wild Type Control	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
Mutant Control	MTB DETECTED VERY LOW;RIF Resistance DETECTED or MTB DETECTED LOW;RIF Resistance DETECTED or MTB DETECTED MEDIUM;RIF Resistance DETECTED or MTB DETECTED HIGH;RIF Resistance DETECTED	Passed
Negative	MTB NOT DETECTED	Passed

✓ If checked, this document is produced electronically and therefore valid without a wet signature

Mustafa Didehvar
Mustafa Didehvar (Dec 12, 2024 13:25 GMT+1)

Signature of Quality Assurance,

Date

Name: Mustafa Didehvar

Title: QA Analyst