



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/RIF

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

Kit Lot No.: 1001441563

Cartridge Lot No.: 44403

Kit Expiration Date: 2026-07-26

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna

Sunnyvale

Lodi

Functional Testing according to D31503 Rev. AA₁

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MTB Detected; Rif Resistance not detected	Passed
Negative	MTB not detected	Passed

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

Signature of Quality Assurance,

14 AUG 2024

Date

Name: Sayed Safdari

Title: Quality Systems Specialist I