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.: 1001451829

Cartridge Lot No.: 44701

Kit Expiration Date: 2026-09-27

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. AA.1

Test Description	*Acceptance Criteria*	*Test Result*
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

10/20/24

Signature of Quality Assurance, **Date**

Name: Hera Marinas

Title: Quality Systems Specialist