

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 Nam	ie: Xpert® MTB	RIF Ultra	
Cepheid Catalogue Part No.:		GXMTB/RIF-ULTRA-50	~
Kit Lot No.:	1001424173		
Cartridge Lo	ot No.: 48009		

Kit Expiration Date: 2025 10 05

Legal Manufacturer	Manufacturing Facility		
Cepheid AB	Cepheid	Solna	Sunnyvale
Röntgenvägen 5	121 N Guild Avenue	Some	O Buildy vale
SE-17154 Solna	Lodi, CA 95240		
Sweden	USA	Lodi	

Functional Testing according to D25862, Rev. AN

Test Description	Acceptance Criteria	Test Result	
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 of MTB DETECTED LOW;RIF Resistance DETECTED of MTB DETECTED MEDIUM;RIF Resistance DETECTED of MTB DETECTED HIGH;RIF Resistance DETECTED	Passed	
Negative	Negative MTB NOT DETECTED		

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

Signature of Quality Assurance,

Date

Name: Ramon De Leon

Title: Quality Systems Specialist