

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 Device Regulations (CMDR).

Product Name: Xpert® MTB/RIF Ultra			
Cepheid Catalogue Part No.: GXMTB/RIF-ULTRA-10			
Kit Lot No.: 1000419902			
Cartridge Lot No.: 32912			
Kit Expiration Date: 2023-11-19			
Legal Manufacturer	Manufacturing Facility	Solna	
Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden		

Functional Testing

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 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

Signature of Quality Assurance	Date
Name: Wafa Qasim	
Title: QA Analyst	