

Name: Blia Her

Title:

Quality System Specialist

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 dian Medical Devices	Quality System Requirements, ISO 13485, European IVD Regulations (CMDR).	Directive and the Cana-
Product Name: Xper	t® MTB/RIF Ultra	
Cepheid Catalogue P	art No.: GXMTB/RIF-ULTRA-50	4
Kit Lot No.: 100072		
Cartridge Lot No.: 4	4412	
Kit Expiration Date:		*
T 1 N/I C - 4		A
Legal Manufacture Cepheid AB Röntgenvägen 5	<u>Manufacturing Facility</u> Cepheid 121 N Guild Avenue	Solna Sunnyval
SE-17154 Solna	Lodi, CA 95240	
Sweden	USA	Lodi
Functional Testing of	according to D25862, Rev. AK	
Test Description	Acceptance Criteria	Test Result
Wild Type Control	MTB DETECTED VERY LOW; Rif Resistance NOT DETECTED of 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	MTB NOT DETECTED	Passed
If checked, this do	cument is produced electronically and therefore valid without	out a wet signature