



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.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Solna Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
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

20191120

Date

Name:

Title: