Cepheid®

CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the cartridges specified below conform 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 Cartridges

Cepheid Part No.: 700-7773 - ASSY,10 CART POUCH,MTB/RIF BANGALORE

Lot No.: 1001470356

Cartridge Lot No.: 95119

Manufacuring Date: 2025-01-31

Expiration Date: 2027-01-17

Manufacturing Facility (●) Solna ( ) Sunnyvale ( ) Newark

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Positive	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
Negative	MTB NOT DETECTED	Passed

2025-02-07

Signature of Quality Assurance **Date**

Name: Alexander Avramidis

Title: QA Analyst