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 Name: Xpert® GBS LB XC

Cepheid Catalogue Part No.: GXGBSLBXC-10

Kit Lot No.: 1001452115

Cartridge Lot No.: 13002

Kit Expiration Date: 2026-09-27

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

(●) Solna ( ) Sunnyvale ( ) Newark ( ) Lodi

Functional Testing according to D68621 Rev: A

Test Description	*Acceptance Criteria*	*Test Result*
Positive	GBS POSITIVE	Passed
Negative	GBS NEGATIVE	Passed

☐ If checked this document is produced electronically and valid without a wet signature.

RFD 20241017

Signature of Quality Assurance, Date

Name: Robert Fiedler

Title: QA Analyst