



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.: 1001460207

Cartridge Lot No.: 13301

Kit Expiration Date: 2026-11-22

Legal Manufacturer Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

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

Functional Testing according to D68621 Rev: A

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	GBS POSITIVE	Passed
Negative	GBS NEGATIVE	Passed

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

M. Vahid 2024/2/11
Signature of Quality Assurance, Date

Name: Samaneh Vahid

Title: Senior QA Analyst