



## 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.:** 1001465006

**Cartridge Lot No.:** 13501

**Kit Expiration Date:** 2026-12-20

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

**Manufacturing Facility**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

Solna  Sunnyvale

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.

20250109

**Signature of Quality Assurance, Date**

**Name:** Sara Mustafa Abdulla

**Title:** QA Analyst

P/N 302-7925 Rev. D