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

Cepheid Catalogue Part No.: GXGBS-100N-10

Kit Lot No.: 1001461745

Cartridge Lot No.: 24705

Kit Expiration Date: 2026-05-24

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

○ Solna ◉ Sunnyvale

○ Lodi

Functional Testing according to D16903, Rev. AB

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

■ If checked, this document is produced electronically and therefore valid without a wet signature

Molly Doan
Molly Doan (Dec 4, 2024 14:00 PST)

Dec 4, 2024

Signature of Quality Assurance, **Date**

Name: Molly Doan

Title: Quality System Specialist

301-6220 Rev B GBS

Final Audit Report 2024-12-04

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