



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.: 1001471335

Cartridge Lot No.: 24708

Kit Expiration Date: 2026 07 26

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA



Solna



Sunnyvale



Lodi

Functional Testing according to D16903, Rev. AB

<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 therefore valid without a wet signature

Signature of Quality Assurance,

Date

Name: Crystal Sysenglath

Title: Quality Systems Specialist