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® Xpress GBS

Cepheid Catalogue Part No.: **XPRSGBS-CE-10**

Kit Lot No.: 1001446996

Cartridge Lot No.: 12901

Kit Expiration Date: 2026-09-06

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

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

Functional Testing according to D37988 Rev: E

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.

2024-09-23
Signature of Quality Assurance, Date

Name: Alexander Avramidis

Title: QA Analyst

P.N 302-8725 Rev. A