Cepheid

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 Device Regulations (CMDR).

Product Name: Xpert® GBS

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

Kit Lot No.: 1000640896

Cartridge Lot No.: 23102

Kit Expiration Date: 2024-06-09

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ○ Solna ◉ Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

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

01/05/2023

Signature of Quality Assurance **Date**

Name:

Title: