



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.: 1001465005

Cartridge Lot No.: 13402

Kit Expiration Date: 2026-12-13

<u>Legal Manufacturer</u>	<u>Manufacturing Facility</u>	● Solna	Sunnyvale	Newark
Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden			Lodi

Functional Testing according to D37988 Rev: F

<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.

Mustafa Didehvar
Mustafa DidehVar (Dec 29, 2024 11:28 GMT+1)

Signature of Quality Assurance, Date

Name: Mustafa Didehvar

Title: QA Analyst

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