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® vanA

Cepheid Catalogue Part No.: GXVANA-10

Kit Lot No.: 1001455891

Cartridge Lot No.: 07902

Kit Expiration Date: 2025-10-19

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 D16902, Rev. U

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

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

ThuyTien Nguyen
ThuyTien Nguyen (Nov 2, 2024 10:29 PDT)

Nov 2, 2024

Signature of Quality Assurance **Date**

Name: ThuyTien Nguyen

Title: Quality Systems Specialist

GXVANA-10 1001455891

Final Audit Report 2024-11-02

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