



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[®] vanA/vanB

Catalogue Part No.: GXVANA/B-CE-10

Kit Lot No.: 1001452600

Cartridge Lot No.: 14603

Kit Expiration Date: 2025-10-05

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	vanA POSITIVE; vanB POSITIVE	Passed
Negative	vanA NEGATIVE; vanB NEGATIVE	Passed

If checked this document is produced electronically and valid without a wet signature.

Lava Maroof

Lava Maroof (Oct 16, 2024 10:35 GMT+2)

Signature of Quality Assurance

Date

Name: Lava Maroof

Title: QA Analyst