



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® Norovirus

Catalogue Part No.: GXNOV-10

Kit Lot No.: 1001468513

Cartridge Lot No.: 19402

Kit Expiration Date: 2026-04-12

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Solna

Sunnyvale

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
LOW Positive	NORO GI DETECTED;NORO GII DETECTED	Passed
HIGH Positive	NORO GI DETECTED;NORO GII DETECTED	Passed
Negative	NORO GI NOT DETECTED;NORO GII NOT DETECTED	Passed

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

 2025-01-17

Signature of Quality Assurance

Date

Name: Alexander Avramidis

Title: QA Analyst

PN 301-6261 Rev. B