



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-CE-10

Kit Lot No.: 1001450584

Cartridge Lot No.: 19204

Kit Expiration Date:2026-01-11

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>
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.

Robert Fiedler
Robert Fiedler (Oct 14, 2024 16:48 GMT+2)

Signature of Quality Assurance

Date

Name: Robert Fiedler

Title: QA Analyst