



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.: 1001465130

Cartridge Lot No.: 19503

Kit Expiration Date: 2026-06-07

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.

 2025-01-14

Signature of Quality Assurance

Date

Name: Alexander Avramidis

Title: QA Analyst

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