Cepheid®

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® Norovirus

Cepheid Catalogue Part No.: GXNOV-CE-10

Kit Lot No.: 1000172515

Cartridge Lot No.: 15202

Kit Expiration Date: 2020-11-22

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility ◉ Solna ○ Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
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

20191017

Signature of Quality Assurance **Date**

Name: Samaneh Vahid

Title: QA Analyst

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