



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.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

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



Signature of Quality Assurance

20191001

Date

Name:

Title: