Cepheid

CERTIFICATE OF ANALYSIS

This letter is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System. The Cepheid Quality System is in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485:2012, European IVD Directive and the Canadian Medical Device Regulations (CMDR).

Product Name:
KIT,GX,10-TEST,EBOLA,CE-IVD

Cepheid Catalogue Part No.:
GXEBOLA-CE-10

Kit Lot No.: **1000180647**

Kit Expiration Date: **2020-11-15**

Cartridge Lot No.: 15201

Legal Manufacturer:
Cepheid AB
Röntgenvägen 5
P.O. Box 1427
SE-171 27 Solna
Sweden

Manufacturing Facility:
Cepheid AB
Röntgenvägen 5
P.O. Box 1427
SE-171 27 Solna
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Negative	Ebola GP NOT DETECTED;Ebola NP NOT DETECTED	Passed
LOW Positive	Ebola GP DETECTED;Ebola NP DETECTED	Passed
HIGH Positive	Ebola GP DETECTED;Ebola NP DETECTED	Passed

20200102

Signature of Quality Assurance, Date

Name: Marie Bah

Title: QA Manager Release