



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® Ebola Assay

Catalogue Part No.: GXEBOLA-10

Kit Lot No.: 1001456569

Cartridge Lot No.: 18701

Kit Expiration Date: 2025-11-16

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>
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

If checked this document is produced electronically and valid without a wet signature.

Samaneh Vahid Gharavi

Samaneh Vahid Gharavi (Dec 2, 2024 13:18 GMT+1)

Signature of Quality Assurance

Date

Name: Samaneh Vahid

Title: Senior QA Analyst