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® SA Nasal Complete

Cepheid Catalogue Part No.: GXSACOMP-CE-10

Kit Lot No.: 1000242183

Cartridge Lot No.: 23406

Kit Expiration Date: 2022-12-25

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility ○ Solna ◉ Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Positive	MRSA Positive; SA Positive	Passed
Negative	MRSA Negative; SA Negative	Passed

03 Feb 21

Signature of Quality Assurance **Date**

Name: Molly Doan

Title: Quality System Specialist III