

Functional Testing

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-120	
Kit Lot No.: 1000171599	
Cartridge Lot No.: 21712	
Kit Expiration Date: 2021-08-08	
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Manufacturing Facility Solna Sunnyvale Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA

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

Nambran 5	2500719
Signature of Quality Assurance	Date
Name: Tann Tran	
Title: Quality Systems Specialist	