

Product Name: Xpert® SA Nasal Complete

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).

Cepheid Catalogue Part No.: GXSACOMP-CE-10			
Kit Lot No.: 1000319627			
Cartridge Lot No.: 24412			
Kit Expiration Date: 2023-10-08			
Legal Manufacturer	Manufacturing Facility	○ Solna	Sunnyvale
Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	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	

par	dinever	10/21/	2021
Signature of Q	uality Assurance		Date
Name: Pauli	ine Vu		
Title: Qualit	y Systems Special	list	