 S GR11.1 DOC 127 REV04 OF 30/09/2019		CERTIFICATE OF STERILITY AND QUALITY ASSURANCE		N° 19-CRT05409
COPAN CODE	CEPHEID CODE	LOT N°	EXP. DATE	
3U009N.PH	3U009N.PH	191665600	30/04/2021	

DEVICE DESCRIPTION:	Xpert Nasal Sample Collection Kit for Viruses
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- Appearance: The medium is clear and light rose-orange in color.
- Packaging date: 08/10/2019
- pH of the medium at 25°C acceptability limits 7,3 ± 0,2: passed
- USP Membrane Filtration Sterility Test: Passed
- FLOQSwabs have been EO treated.
 Biological Indicator control for EO treatment using *B. atrophaeus* 10⁶ sporestrip: no growth after validated incubation conditions at 37°C ± 2°C.
 Sterilisation procedure is validated in conformity with ISO 11135:2014.
- Culture Response:
 Swabs were inoculated with the test organisms and placed in the UTM medium. Good recovery of all organisms was obtained after 48 hours at 2-6°C and 20-24°C.

Test Organisms

Herpes Simplex Virus Type 2	ATCC VR-734
Influenza A	ATCC VR-1679
Cytomegalovirus	ATCC VR-977
Coxsackievirus B1	ATCC VR-28
<i>Chlamydia trachomatis</i>	ATCC VR-880
<i>Mycoplasma pneumoniae</i>	ATCC 15531

7. Animal Origin

Country of bovine origin components is provided below:

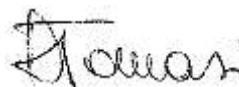
Material	Country of Origin	Animal Source	Comments
BSA	U.S.A.	Bovine	None

All reported results were obtained at the time of lot release. Goods has been manufactured according to the EN ISO 13485:2016 system. By signing below, Copan Italia SpA certifies that the above quality requirements have been met and all information stated above is correct.

Made by COPAN ITALIA SpA, via F.Perotti 10, 25125 Brescia, Italy for CEPHEID. Includes Flocked Swab made by COPAN FLOCK TECHNOLOGIES srl, via F. Perotti 18, 25125 Brescia, Italy

28/10/2019

Certificate Date of Issue



Chief Quality Officer
 Copan Italia SpA