 S GR11.1 DOC 222 REV01 of 30/09/2019		<b>CERTIFICATE OF STERILITY AND QUALITY ASSURANCE</b>		N° <b>19-CRT05836</b>
<b>COPAN CODE</b>	<b>CEPHEID CODE</b>	<b>LOT N°</b>	<b>EXP. DATE</b>	
3U009N.PH	3U009N.PH	191908300	30/04/2021	

<b>DEVICE DESCRIPTION:</b>	Xpert Nasal Sample Collection Kit for Viruses
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1. Appearance: The medium is clear and light rose-orange in color.
2. Packaging date: 25/10/2019
3. pH of the medium at 25°C acceptability limits 7,3 ± 0,2: passed
4. USP Membrane Filtration Sterility Test: Passed
5. FLOQSwabs have been EO treated.  
Biological Indicator control for EO treatment using *B. atrophaeus*10<sup>6</sup> sporestrip: no growth after at least 2 days at 37°C ± 2°C.
6. 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:

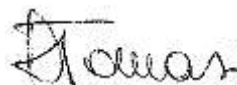
Material	Country of Origin	Animal Source	Comments
<b>BSA</b>	<b>U.S.A.</b>	<b>Bovine</b>	<b>None</b>

All reported results were obtained at the time of lot release. Goods has been manufactured according to the 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.

18/11/2019
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Certificate Date of Issue



Chief Quality Officer  
Copan Italia SpA