

CERTIFICATE OF STERILITY AND QUALITY ASSURANCE

REV09 OF 02/05/2024

CODE	LOT N°	EXP. DATE
359C	240587600	22/09/2025

DEVICE DESCRIPTION:	UTM MINI RT-1ML Medium For Virus, Chlamydia, Mycoplasma and
	Ureaplasma Specimens Single Plastic Flocked swab Velvet Tipped

- 1. Appearance: The medium is clear and light rose-orange in color.
- 2. Manufacture date: 22/03/2024
- 3. pH of the medium at 25°C acceptability limits 7,3 \pm 0,2: passed
- 4. USP Membrane Filtration Sterility Test: Passed
- 5. 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
Chlamydia trachomatis	ATCC VR-880
Mycoplasma pneumoniae	ATCC 15531

All reported results were obtained following internal SOP instructions.

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.

	07/05/2024	
C	ertificate Date of	Issue

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Quality Representative Copan Italia SpA Via F.Perotti 10 - 25125, Brescia - Italy