

 S GR11.6 DOC 25 REV09 OF 02/05/2024	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 24-CRT05034
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CODE	LOT N°	EXP. DATE
330C	2414405	30/04/2026

DEVICE DESCRIPTION:	UTM-RT Medium For Virus, Chlamydia, Mycoplasma and Ureplasma Specimens
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1. Appearance: The medium is clear and light rose-orange in color.

2. Manufacture date: 30/10/2024

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
<i>Chlamydia trachomatis</i>	ATCC VR-880
<i>Mycoplasma pneumoniae</i>	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.

28/11/2024

Certificate Date of Issue



Quality Representative

Copan Italia SpA

Via F.Perotti 10 – 25125, Brescia - Italy