

 S GR11.1 DOC 121 REV03 OF 21/03/2022	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 24-CRT03951
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COPAN CODE	CEPHEID CODE	LOT N°	EXP. DATE
8U003N.PH	URINE/A-50	241513200	21/10/2027

DEVICE DESCRIPTION:	Xpert Urine Specimen Collection Kit
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1. Manufacture date: 21/10/2024
2. pH of the medium, acceptability limits pH 7,95 - 8,35 at 20,0-26,0 °C: passed
3. Pipettes have been irradiated by gamma radiation.
The applied dose range is validated to guarantee the Sterility Assurance Level SAL 10⁻⁶.
Sterilisation procedure validated in conformity with BS EN ISO 11137-1:2015 and BS EN ISO 11137-2:2015.

All reported results were obtained at the time of lot release.
Goods have 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



Quality Representative
Copan Italia SpA
Via F.Perotti, 10 – 25125 Brescia (Italy)

Certificate Issue Date
06/11/2024