

CERTIFICATE OF ANALYSIS

MODEL: BioCapt® Single-Use Sampler (*) **PRODUCT CODE:** 79001209 **BATCH:** 24A2701

MEDIA: Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Histidine + 0.05% S-Thiosulfate

MANUFACTURING DATE: 27 Jan 2024

EXPIRY DATE: 27 Jan 2025

STORAGE CONDITIONS: at 2-25°C until expiry date

(*) BioCapt®: Registered trademark.

BioCapt Single Use: U.S. Patents 10,345,200 and 11,231,345.

www.pmeasuring.com/trademarks-and-patents/

CHEMICAL/PHYSICAL TESTS

TESTS	SPECIFICATION	RESULT
Appearance	Light amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	30ml±1ml	Conforms
Media composition	TSA+NEUTRALIZERS (see technical data sheet) Medium is prepared utilizing raw materials declared to be BSE-TSE FREE by the manufacturer	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	≥10 KGy	Conforms Irradiation certificate Nr: 3505088

STERILITY CONTROL (performed before gamma irradiation)

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 7 days 22.5±2.5°C aerobic for 7 days	No growth	Conforms

FERTILITY – GROWTH PROMOTION TEST (performed after gamma irradiation)

CONTROL STRAIN	MEDIUM INOCULATION LEVEL	INCUBATION CONDITIONS	RECOVERY SPECIFICATIONS	RECOVERY RESULTS	RESULT
E. coli ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	96.5%	Conforms
P. aeruginosa ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	85.8%	Conforms
S. aureus ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	80.6%	Conforms
B. subtilis ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	95.3%	Conforms
C. albicans ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	113.2%	Conforms
A. brasiliensis ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	93.0%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	90.5%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	88.8%	Conforms

Growth Promotion Test in accordance to harmonised EP – USP Pharmacopoeias chapter, by quantitative surface plating method.

Recovery: results as cfu enumeration on test batch agar plates x 100/cfu enumeration on reference tests.

Reference medium for recovery tests: Tryptone Soya Agar for all Bacteria and Sabouraud Dextrose Agar for Yeast & Mold species.

ATCC is registered trademark of American Type Culture Collection.

DATE ANALYSIS START: 27 Jan 2024

BATCH STATUS: Approved

QUALITY CONTROL: Cinzia Bovio

QUALITY ASSURANCE: Andrea Farronato

DATE ANALYSIS END: 8 Mar 2024

DATE OF BATCH RELEASE: 11 Mar 2024

SIGNATURE:

SIGNATURE:

Certificate of Processing

STERIGENICS Via Marzabotto, 4 Minerbio BO 40061 Italy
 TEL 39 051-6605998 FAX 39 051-6605574 www.sterigenics.com

R55480102

1-Mar-24 8:25:37 GMT

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Customer Name:	ANICRIN SRL	Processing Facility:	Minerbio	Work Order #	3505088
P.O.#	160			Sales Order #	3496250
10-25 kGy		CRIN GAMMA TREATMENT	Irradiation Date/Time:	29-Feb-24 04:36:59 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402614	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
102.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402613	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
103.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402615	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
104.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402617	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
105.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402619	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
106.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402618	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
107.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402616	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
108.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402620	21.02.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
	8	PL	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail
450.00	Minimum Dose	10.0 kGy	25.0 kGy	15.5 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	20.3 KGY	Pass

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: MILENA TAMPELLINI
 Reason: Work Order Completions

Date: 1-Mar-24 08:22:13 GMT



anicrin s.r.l.

Company Subsidiary of
IMI REAL ESTATE s.r.l.

Via Moglianese, 44/L
30037 Scorzè (VE)

t. + 39 (0)41 445660
e. info@anicrin.com
www.anicrin.com

VAT number: 02887950273
Unique Code: 7HE8RN5



A.01 Mod.0
R.29 Mod.0

Documento	Numero	Data	Pagina
DdT	160	20/02/2024	1 / 1
Partita IVA IT 00500911201	Codice Fiscale		
Causale Trasporto Uscita in C/Lavoro	Modalità di consegna		
Pagamento			
Banca d'Appoggio			
Banca			

Spett.le
Sterigenics Italy Spa
Via Marzabotto 4
40061 Minerbio BO
Italia

Ref.	Descrizione	UM	Quantità
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A2401 Qtà: 1.728	BOX 24	NR 1.728
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A2402 Qtà: 1.728	BOX 24	NR 1.728
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A2501 Qtà: 1.800	BOX 25	NR 1.800
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A2502 Qtà: 1.800	BOX 25	NR 1.800
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A2601 Qtà: 1.800	BOX 25	NR 1.800
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2301 Qtà: 1.800	BOX 25	NR 1.800
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2701 Qtà: 1.656	BOX 23	NR 1.656
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2902 Qtà: 1.656	BOX 23	NR 1.656
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24B0101 Qtà: 1.800	BOX 25	NR 1.800
79001409	Biocapt Single Use Sabauraud Dextrose Agar with Neutralizers Lotto: 24B0201 Qtà: 1.872	BOX 26	NR 1.872

Contratto 2821/2024

Note Contratto 2821/2024				
Vettore	Peso Netto	Aspetto Esteriore dei Beni		Trasporto a cura del
	Peso Lordo	Pallets 8	Colli	Inizio Trasporto
AVVISO IMPORTANTE: i Vs. dati anagrafici e la partita iva che appaiono sul presente documento saranno quelli che verranno utilizzati, salvo Vs. diversa precisazione, ai effetti dell' Art. 2 DPR 633/72. Con questo avviso CI consideriamo esonerati da qualsiasi responsabilità prevista dall'Art.41 DPR 633/72.		Firma Conducente (o Vettore)		Firma Destinatario