

CERTIFICATE OF ANALYSIS

MODEL: BioCapt® Single-Use Sampler (*) **PRODUCT CODE:** 79001201 **BATCH:** 24A1801
MEDIA: Tryptone Soya Agar
MANUFACTURING DATE: 18 Jan 2024
EXPIRY DATE: 18 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/

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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 (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: 3501429	
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%	92.6%	Conforms
P. aeruginosa ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	104.3%	Conforms
S. aureus ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	100.0%	Conforms
B. subtilis ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	84.1%	Conforms
C. albicans ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	96.2%	Conforms
A. brasiliensis ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	100.0%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	82.8%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	91.3%	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: 18 Jan 2024

BATCH STATUS: Approved

QUALITY CONTROL: Cinzia Bovio

QUALITY ASSURANCE: Andrea Farronato

DATE ANALYSIS END: 23 Feb 2024

DATE OF BATCH RELEASE: 23 Feb 2024

SIGNATURE:

SIGNATURE:

Cinzia Bovio
Farronato Andrea

Certificate of Processing

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

R55480102

15-Feb-24 9:36:53 GMT

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Customer Name: ANICRIN SRL EUR IT SCORZE
P.O.# 129

Processing Facility: Minerbio

Work Order # 3501429
Sales Order # 3492504

10-25 kGy

CRIN GAMMA TREATMENT

Irradiation Date/Time:

14-Feb-24 11:24:58 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	WWW0004402605	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
102.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402606	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
103.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402607	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
104.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402608	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
105.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402609	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
106.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402610	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
107.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402611	129.2024
	Dose Map		270_CRIN_984/24	Std cycle 15 kGy		
108.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402612	129.2024
	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	14.2 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	19.1 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: VALERIA LOSITO
 Reason: Work Order Completions

Date: 15-Feb-24 09:36:13 GMT



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A.01 Mod.0

R.29 Mod.0

Documento DdT	Numero 129	Data 12/02/2024	Pagina 1 / 1	Spett.le Sterigenics Italy Spa Via Marzabotto 4 40061 Minerbio BO Italia
Partita IVA IT 00500911201	Codice Fiscale			
Causale Trasporto Uscita in C/Lavoro	Modalità di consegna			
Pagamento				
Banca d'Appoggio				
Banca				

Ref.	Descrizione	UM	Quantità
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A1701 Qtà: 3.312	BOX 46	NR 3.312
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A1801 Qtà: 1.728	BOX 24	NR 1.728
79001201	BioCapt Single Use Tryptone Soy Agar box of 72 pcs Lotto: 24A1802 Qtà: 1.656	BOX 23	NR 1.656
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A1901 Qtà: 1.656	BOX 23	NR 1.656
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2001 Qtà: 1.584	BOX 22	NR 1.584
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2201 Qtà: 1.800	BOX 25	NR 1.800
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2202 Qtà: 1.656	BOX 23	NR 1.656
79001209	BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs Lotto: 24A2302 Qtà: 1.656	BOX 23	NR 1.656
	confezione di contro campioni		2
	confezione piastre per analisi post irraggiamento		3
	Contratto 2821/2024		

Note				
Contratto 2821/2024				
Vettore KIKO SPEED SRL VIA TRIESTE 14 36061 BASSANO DEL GRAPPA VI Partita IVA: IT 02967650249	Peso Netto	Aspetto Esteriore dei Beni		Trasporto a cura del
	Peso Lordo	Pallets 8	Colli	Inizio Trasporto 12/02/2024 12.00
AVVISO IMPORTANTE: i Vs. dati anagrafici e la partita iva che appaiono sul presente documento saranno quelli che verranno utilizzati, salvo Vs. diversa precisazione, agli 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