

CERTIFICATE OF ANALYSIS

MODEL: BioCapt® Single-Use Sampler (*) **PRODUCT CODE:** 79001209 **BATCH:** 24A1901
MEDIA: Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Histidine + 0.05% S-Thiosulfate
MANUFACTURING DATE: 19 Jan 2024
EXPIRY DATE: 19 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: 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%	96.6%	Conforms
P. aeruginosa ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	75.7%	Conforms
S. aureus ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79.2%	Conforms
B. subtilis ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79.7%	Conforms
C. albicans ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	92.4%	Conforms
A. brasiliensis ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	88.5%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	92.4%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	93.2%	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: 19 Jan 2024

DATE ANALYSIS END: 23 Feb 2024

BATCH STATUS: Approved

DATE OF BATCH RELEASE: 23 Feb 2024

QUALITY CONTROL: Cinzia Bovio

SIGNATURE:

QUALITY ASSURANCE: Andrea Farronato

SIGNATURE:

Frascati (RM) – Italy Feb 13, 2024

To whom it may concern

Subject: BioCapt® Single Use Sampler Production Process

Temporary Deviation #NC 10-2024

Product name (s): BioCapt® Single-Use Sampler (BCSUs) manufactured by Anicrin Srl on behalf of Particle Measuring Systems – Absence of holes in the primary packaging.

Dear Customer,

We hereby inform you that due to the temporary disabling of a specific functionality of the Packaging Machine, in some batches produced in January 2024 it was not possible in the internal bags to make holes used by Customers to hang the triplets.

The lots involved by this temporary event are:

BCSU product type	Lot#
TSA	24A1701
TSA + NEUTRAL	24A1901
TSA + NEUTRAL	24A2001
TSA + NEUTRAL	24A2201
TSA + NEUTRAL	24A2202
TSA + NEUTRAL	24A2302

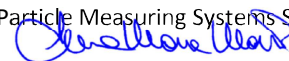
This event has no impact on the integrity of the packaging and the quality/performance of the culture media; therefore, **the involved batches will be regularly released.**

The functionality of the Packaging Machine was completely re-established and therefore the subsequent batches produced returned to having the standard configuration with the holes in the two internal bags.

Your regular sales contacts and the Quality Assurance department of Particle Measuring Systems are available for any further questions and details on this matter.

Best Regards,

Anna Maria Motti
Quality Assurance Manager
Particle Measuring Systems Srl



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		
102.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402606	129.2024
			Dose Map	270_CRIN_984/24		
103.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402607	129.2024
			Dose Map	270_CRIN_984/24		
104.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402608	129.2024
			Dose Map	270_CRIN_984/24		
105.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402609	129.2024
			Dose Map	270_CRIN_984/24		
106.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402610	129.2024
			Dose Map	270_CRIN_984/24		
107.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402611	129.2024
			Dose Map	270_CRIN_984/24		
108.000	1	PL	2821/24_984/24	BioCapt Single Use	WWW0004402612	129.2024
			Dose Map	270_CRIN_984/24		
	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	Numero	Data	Pagina	Spett.le Sterigenics Italy Spa Via Marzabotto 4 40061 Minerbio BO Italia
DdT	129	12/02/2024	1 / 1	
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