

CERTIFICATE OF ANALYSIS

MODEL: BioCapt® Single-Use Sampler (*) **PRODUCT CODE:** 79001210 **BATCH:** 24B2301
MEDIA: Tryptone Soya Agar+0.07% Lecithin+0.5% Tween80+0.1% L-Histidine+0.05% S-Thiosulfate+1000UI/Lt Lactamator™
MANUFACTURING DATE: 23 Feb 2024
EXPIRY DATE: 23 Feb 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+LACTAMATOR™ (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: 1856/2024

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%	98.2%	Conforms
P. aeruginosa ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79.5%	Conforms
S. aureus ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79.3%	Conforms
B. subtilis ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	94.2%	Conforms
C. albicans ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	98.6%	Conforms
A. brasiliensis ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	96.6%	Conforms
Environmental strain #1	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	108.9%	Conforms
Environmental strain #2	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	90.9%	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: 23 Feb 2024

DATE ANALYSIS END: 03 Apr 2024

BATCH STATUS: Approved

DATE OF BATCH RELEASE:

QUALITY CONTROL: Cinzia Bovio

SIGNATURE: 

QUALITY ASSURANCE: Andrea Farronato

SIGNATURE: 

gammatom^{S.r.l.}

Divisione Irraggiamento - Irradiation Department

VIA XXIV MAGGIO, 14 - 22070 GUANZATE (CO)

Phone: +39 031 976035 / +39 031 977379

Telefax: +39 031 976524

E-mail : info@gammatom.it

Capitale Sociale € 10.400 i.v.

Codice Fiscale e P.IVA 03165630157

Reg. Imp. MI n. 77363 - R.E.A. MI n. 411471

Sede legale: 20121 Milano - Piazza Cavour, 3

SPETT.LE

ANICRIN SRL

**VIA MOGLIANESE 44/L 30037 SCORZE'
(VE) Italia**

SMCC n°: **SMCC-02026/24.01**

Numero Attestato / Certificate number

1856/2024

Data Redazione Attestato / Certificate drafting date

25/03/2024

Attestato di irraggiamento / Irradiation certificate

Codice Articolo Article Code	Descrizione Description	Quantità Colli Quantity of Boxes
ANRCAMP	CAMPIONE - ANALISI Documento di trasporto n°/Waybill n°: 243 Trattamento n°/Treatment n° 203/24 del 21.03.2024 Dose nominale/Nominal dose: 10.0 kGy Lotto n°/Batch n°: 24B2302 24B2301	1
ANRCAMP	CONTRO CAMPIONE Documento di trasporto n°/Waybill n°: 243 Trattamento n°/Treatment n° 203/24 del 21.03.2024 Dose nominale/Nominal dose: 10.0 kGy Lotto n°/Batch n°: 24B2302 24B2301	1
ANRTERRENI1/6-10	TERRENI DI COLTURA Documento di trasporto n°/Waybill n°: 243 Trattamento n°/Treatment n° 203/24 del 21.03.2024 Dose nominale/Nominal dose: 10.0 kGy Dose min. 10.7 kGy - Dose max. 13.5 kGy Dosimetri/Dosimeters: tipo/type Amber 3042, lotto/batch AE Lotto n°/Batch n°: 24B2302 24B2301 RIF. NS. DDT N. 2221 DEL 25.03.2024	98

AZIENDA CON SISTEMA QUALITÀ CERTIFICATO

UNI CEI EN ISO 13485:2016
UNI EN ISO 22716:2008

Provision of irradiation treatments for sterilization with Co-60 gamma radiation,
according to EN ISO 11137 standard series

gammatom S.r.l.
Quality Assurance
Maria Vittoria Introini

gammatom S.r.l.
Quality Assurance
Cristina Piazza

Attestato non firmato perché generato dal computer/certificate not signed because computer generated

- Autorizzazione del Ministero dell'Industria del Commercio e dell'Artigianato XIII 407 del 04/10/1999

- Decreto AIFA n° aAPI-8/2023 del 19/01/2023 per il trattamento di materie prime farmacologicamente attive

- Decreto AIFA n° aIM-2/2023 del 03/01/2023

- Certificate of GMP Compliance n. IT-API/23/H/2023

- Certificate of GMP Compliance n. IT/2/H/2023

- Decreto Ministero della Salute N. 07/2014/V del 26/06/2014 per il trattamento di materie prime farmacologicamente attive e di prodotti finiti

- Certificato di conformità alle Norme di Buona Fabbricazione NBF/31/2021/V del 22/06/2021

- Iscrizione albo laboratori altamente qualificati - G.U. n. 283 del 02/12/88

Con il ricevimento del presente certificato il cliente implicitamente accetta il trattamento dei dati personali ivi contenuti ai sensi del D.Lgs. 101/18

Eseguito da Sirtori Ilaria (ilaria.sirtori) il 26/03/2024 14:18:47
Performed by Sirtori Ilaria (ilaria.sirtori) - 26/03/2024 14:18:47