

## CERTIFICATE OF ANALYSIS

**MODEL:** BioCapt® Single-Use Sampler (\*) **PRODUCT CODE:** 79001201 **BATCH:** 24A2402  
**MEDIA:** Tryptone Soya Agar  
**MANUFACTURING DATE:** 24 Jan 2024  
**EXPIRY DATE:** 24 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/](http://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 (see technical data sheet)<br>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<br>Irradiation certificate Nr: 3505088 |          |
| STERILITY CONTROL (performed before gamma irradiation)                |                                                                                                                              |                             |                            |                                                 |          |
| TESTS                                                                 | SPECIFICATION                                                                                                                |                             |                            | RESULT                                          |          |
| 32.5±2.5°C aerobic for 7 days<br>22.5±2.5°C aerobic for 7 days        | No growth                                                                                                                    |                             |                            | Conforms                                        |          |
| FERTILITY – GROWTH PROMOTION TEST (performed after gamma irradiation) |                                                                                                                              |                             |                            |                                                 |          |
| CONTROL STRAIN                                                        | MEDIUM<br>INOCULATION LEVEL                                                                                                  | INCUBATION<br>CONDITIONS    | RECOVERY<br>SPECIFICATIONS | RECOVERY<br>RESULTS                             | RESULT   |
| E. coli<br>ATCC 8739                                                  | 10-100 viable<br>microorganisms                                                                                              | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 94.8%                                           | Conforms |
| P. aeruginosa<br>ATCC 9027                                            | 10-100 viable<br>microorganisms                                                                                              | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 96.5%                                           | Conforms |
| S. aureus<br>ATCC 6538                                                | 10-100 viable<br>microorganisms                                                                                              | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 91.8%                                           | Conforms |
| B. subtilis<br>ATCC 6633                                              | 10-100 viable<br>microorganisms                                                                                              | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 90.6%                                           | Conforms |
| C. albicans<br>ATCC 10231                                             | 10-100 viable<br>microorganisms                                                                                              | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%                | 103.1%                                          | Conforms |
| A. brasiliensis<br>ATCC 16404                                         | 10-100 viable<br>microorganisms                                                                                              | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%                | 87.8%                                           | Conforms |
| Environmental strain<br>#1                                            | 10-100 viable<br>microorganisms                                                                                              | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 92.3%                                           | Conforms |
| Environmental strain<br>#2                                            | 10-100 viable<br>microorganisms                                                                                              | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 93.3%                                           | 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:** 24 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](http://www.sterigenics.com)

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1-Mar-24 8:25:37 GMT  
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|                       |                    |                             |                               |                               |                |
|-----------------------|--------------------|-----------------------------|-------------------------------|-------------------------------|----------------|
| <b>Customer Name:</b> | <b>ANICRIN SRL</b> | <b>Processing Facility:</b> | <b>Minerbio</b>               | <b>Work Order #</b>           | <b>3505088</b> |
| <b>P.O.#</b>          | <b>160</b>         |                             |                               | <b>Sales Order #</b>          | <b>3496250</b> |
| <b>10-25 kGy</b>      |                    | <b>CRIN GAMMA TREATMENT</b> | <b>Irradiation Date/Time:</b> | <b>29-Feb-24 04:36:59 GMT</b> |                |

| 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          |                     |                      |
|           | <b>8</b> | <b>PL</b> | <b>Total</b>         |                           |                     |                      |

### 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.

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Unique Code: 7HE8RN5



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

| Documento                               | Numero               | Data       | Pagina |
|-----------------------------------------|----------------------|------------|--------|
| DdT                                     | 160                  | 20/02/2024 | 1 / 1  |
| Partita IVA<br>IT 00500911201           | Codice Fiscale       |            |        |
| Causale Trasporto<br>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<br>Lotto: 24A2401 Qtà: 1.728                   | BOX 24 | NR 1.728 |
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A2402 Qtà: 1.728                   | BOX 24 | NR 1.728 |
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A2501 Qtà: 1.800                   | BOX 25 | NR 1.800 |
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A2502 Qtà: 1.800                   | BOX 25 | NR 1.800 |
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A2601 Qtà: 1.800                   | BOX 25 | NR 1.800 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2301 Qtà: 1.800 | BOX 25 | NR 1.800 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2701 Qtà: 1.656 | BOX 23 | NR 1.656 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2902 Qtà: 1.656 | BOX 23 | NR 1.656 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24B0101 Qtà: 1.800 | BOX 25 | NR 1.800 |
| 79001409 | Biocapt Single Use Sabauraud Dextrose Agar with Neutralizers<br>Lotto: 24B0201 Qtà: 1.872         | BOX 26 | NR 1.872 |

Contratto 2821/2024

|                                                                                                                                                                                                                                                                                                                       |            |                              |       |                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------------------------|-------|----------------------|
| Note<br>Contratto 2821/2024                                                                                                                                                                                                                                                                                           |            |                              |       |                      |
| Vettore                                                                                                                                                                                                                                                                                                               | Peso Netto | Aspetto Esteriore dei Beni   |       | Trasporto a cura del |
|                                                                                                                                                                                                                                                                                                                       | Peso Lordo | Pallets<br>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.<br>Con questo avviso CI consideriamo esonerati da qualsiasi responsabilità prevista dall'Art.41 DPR 633/72. |            | Firma Conducente (o Vettore) |       | Firma Destinatario   |