

Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers + Lactamator 1000IU</b>	102017036	2017.10.20	2018.07.17

Ref. 19104S (79001210)

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 203.750	12,5	2017.11.14

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	7.3
Appearance of medium	Slightly opalescent	Conforms
Colour of medium	Light amber	Conforms
Filling media volume	30 ml ± 1 ml	Conforms
Media Composition	BSE free	Conforms

**Sterility Control- Absence of contamination (before gamma irradiation)**

32.5 ± 2.5 °C aerobic for 7 days	Conforms
22.5 ± 2.5 °C aerobic for 7 days	Conforms

**Microbiological Performance- Growth Promotion Test (after gamma irradiation)**

 Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP  
 Reference media: Tryptic Soy Agar

**Productivity, Method of control: Quantitative**

Inoculum: 10-100 CFU

Control strains	Incubation	Expected Results	Recovery	Results
<i>Bacillus subtilis</i> ATCC® 6633	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	80%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	93%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	110%	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	95%	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	82%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	108%	Conforms

**RECOVERY:** RESULTS AS CFU ENUMERATION ON TEST BATCH AGAR PLATES x 100/ CFU ENUMERATION ON REFERENCE TESTS.

**REFERENCE MEDIUM FOR RECOVERY TESTS:** TSA FOR ALL BACTERIA AND SDA FOR YEAST AND MOLD SPECIES

ATCC IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION

**Enzymatic Activity, Method of control: Disc diffusion** Inoculum: 10<sup>4</sup>-10<sup>5</sup> CFU

Control strains	Incubation	Antimicrobial agent	Specification	Results
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24 h, 32.5 ± 2.5°C	Penicillin G, P 10 IU	No inhibition	Conforms
		Ampicillin, AMP 10 µg	No inhibition	Conforms
		Cefotaxime, CTX 30 µg	No inhibition	Conforms
		Cefepime, FEP 30 µg	No inhibition	Conforms
		Meropenem, MRP 10 µg	No inhibition	Conforms

**Batch Release**

Approved

Date

2017.11.21

Signature

 Quality Control  
 (D. Vitagliano)



The results reported were obtained at the time of release.

