



Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers + Pyruvate</b>	030218055	2018/03/02	2019/03/02
Ref. 19103S (79001206)			

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 207.687	12,5	2018/04/26

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	7.1
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%	82%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	84%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	97%	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%	102%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	90%	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**

**Batch Release**

Approved			
Date	2018/05/21	Signature	Quality Control (D. Vitagliano)
The results reported were obtained at the time of release.			<i>Dario Vitagliano</i>

