

Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers + Pyruvate</b>	032717021	27.03.2017	2017.09.23
<b>Ref. 19103S (79001206)</b>			

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. <u>198.45</u>	12,5	<u>15/05/2017</u>

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	<u>7.3</u>
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

<b>Sterility Control- Absence of contamination (before gamma irradiation)</b>		
32.5 ± 2.5 °C aerobic for 7 days		Conforms
22.5 ± 2.5 °C aerobic for 7 days		Conforms

<b>Microbiological Performance- Growth Promotion Test (after gamma irradiation)</b>
Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP
Reference media: Tryptic Soy Agar

<b>Productivity, Method of control: Quantitative</b>				
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%	<u>84</u>	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	<u>100</u>	Conforms
<i>Staphylococcus aureus</i> ATCC 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	<u>96</u>	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	<u>87</u>	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	<u>92</u>	Conforms
<i>Aspergillus brasiliensis</i> ATCC 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	<u>96</u>	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	<u>22/05/2017</u>	Signature	Quality Control (D. Vitagliano)
The results reported were obtained at the time of release.			<u>Dario Vitagliano</u>