

Certificate of Quality

Product Name: TSB (25ml Serum BTL) 10/PK
Lot Number: 342681

Product Number: R112758
Expiration Date: 2019-05-16
 (YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Inc., a part of Thermo Fisher Scientific Quality Control specifications and were found to meet performance criteria for this product.

Organism Challenge	ATCC	Results
Aspergillus brasiliensis	16404	Pass
Bacillus subtilis	6633	Pass
Candida albicans	10231	Pass
Escherichia coli	8739	Pass
Pseudomonas aeruginosa	9027	Pass
Staphylococcus aureus	6538	Pass

A pass result indicates the organism produced the expected colony size, number, and morphology, indicative of the challenge organism and level for the media formulation, within the required time period. Inoculation levels of 10-100 CFUs were used and incubation was conducted at 30-35°C for not more than 72 hours for bacteria, and at 20-25°C for not more than 5 days for fungi. The results meet or exceed USP Growth Promotion requirements.

Media Physical Characteristics:

Appearance: Light to Medium Amber, Clear Broth
 pH @ 20-25°C: 7.3 +/- 0.2

Microbial Load Evaluation:

Manufactured lot has been terminally steam processed and statistically sampled. Samples were acceptable for microbial content and aesthetic value following a minimum of 14 days at 20-25°C.

Certificate results were obtained at time of release. End users are encouraged to assure product meets internal standards at time of use.

Signed

 Quality Assurance Supervisor