



## Certificate of Quality

**Product Name:** TSA w/Lec PS80 (500ML Septum) 10/Pk  
**Lot Number:** 845673

**Product Number:** R112718  
**Expiration Date:** 2010-12-02  
(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 Quality Control specifications and were found to meet performance criteria for this product.

Organism Challenge	ATCC	Results
Aspergillus niger	16404	Pass
Bacillus subtilis	6633	Pass
Candida albicans	10231	Pass
Escherichia coli	8739	Pass
Pseudomonas aeruginosa	9027	Pass
Staphylococcus aureus	6538	Pass
Staphylococcus epidermidis*	12228	Good Growth

\*Indicated organism growth promotion performed at 33-37°C for 18-24 hours.

A pass result indicates 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 20-25°C for not more than 72 hours. The results meet or exceed USP Growth Promotion requirements.

### Physical Characteristics:

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

### Microbial Load Analysis:

Manufactured lot has been statistically sampled. Samples were acceptable for microbial content and aesthetic value following a minimum of 72 hours at 30-35°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