



Certificate of Quality

Product Name: NLA-TSA Settling, Sterile, Dbl Bag 100/PK
Lot Number: 074938

Product Number: R111872
Expiration Date: 2011-11-15
(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 |

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

Sterility Assurance Level:

This product has been terminally sterilized to an SAL level of 10⁻⁶ by irradiation exposure to be within 13.0-22.0 kGy. Manufactured lot has been statistically sampled. Samples were acceptable for microbial content and aesthetic value following 7 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