



## Certificate of Quality

**Product Name:** NLA - ^LZ^ 10/PK STERILE SAB DEX  
**Lot Number:** 837124

**Product Number:** R111887  
**Expiration Date:** 2010-01-27  
(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
Candida albicans	10231	Pass
Cryptococcus neoformans	34877	Pass
Trichophyton mentagrophytes	9533	Pass

A pass result indicates organism produced the expected colony size, number and morphology indicative of the challenge organism and level for the medium formulation, within the required time period. Inoculation levels of 10-100 CFUs were used for C. albicans and C. neoformans, 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: 5.6+/- 0.2

### Sterility Assurance Level:

This product has been terminally sterilized to an SAL level of 10<sup>-6</sup> 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