

Certificate of Quality

Product Name: Triple Wrap Settle TSA w/Neut 100/pk
Lot Number: 242711

Product Number: R111TW2
Expiration Date: 2025-12-29
(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
<i>Bacillus subtilis</i>	6633	Pass
<i>Escherichia coli</i>	8739	Pass
<i>Pseudomonas aeruginosa</i>	9027	Pass
<i>Staphylococcus aureus</i>	6538	Pass
<i>Staphylococcus epidermidis</i>	12228	Pass
<i>Kocuria rhizophila</i>	9341	Pass
<i>Clostridium sporogenes</i>	19404	Pass
<i>Candida albicans</i>	10231	Pass
<i>Aspergillus brasiliensis</i>	16404	Pass

A pass result indicates organism produced the expected morphology indicative of the challenge organism within the required time period. Inoculation levels of 10-100 CFUs were utilized for challenge testing. All bacteria are incubated at 30-35°C for not more than 72 hours and fungi were incubated at 30-35°C for not more than 5 days. Additionally, *B.subtilis* was incubated at 20-25°C for not more than 72 hours and fungi were incubated at 20-25°C for not more than 5 days. The results meet USP Growth Promotion requirements.

Physical Characteristics:

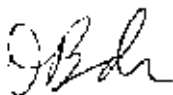
Appearance: Light to Medium Amber, Clear Agar
pH @ 20-25°C: 7.3 +/- 0.2

Sterility Assurance:

This product has been terminally sterilized by irradiation exposure within the range of 14.5-22.0 kGy. Manufactured lot has been statistically sampled prior to irradiation. Samples were acceptable for microbial content and aesthetic value following 7 days of incubation at 20-25°C and 7 days of incubation 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



Senior Quality Assurance Engineer