

Certificate of Quality

Product Name: VERSATREK MYCO BOTTLES
Lot Number: 545023

Product Number: 7111-42
Expiration Date: 2016-02-16
(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 Quality Control specifications and were found to meet performance criteria for this product.

| Organism Challenge | ATCC | Performance Criteria |
|------------------------------|-------------|-----------------------------|
| Mycobacterium fortuitum | 6841 | Positive within 14 Days |
| Mycobacterium intracellulare | 13950 | Positive within 14 Days |
| Mycobacterium kansasii | 12478 | Positive within 14 Days |
| Mycobacterium scrofulaceum | 19981 | Positive within 14 Days |
| Mycobacterium tuberculosis | 25177 | Positive within 14 Days |

Physical Characteristics:

| | |
|--------------------|---|
| Media Appearance: | Colorless to Faint Amber, Clear Broth with No Significant Precipitate |
| Sponge Appearance: | Yellow to Orange with No discoloration |
| pH @ 20-25°C: | 6.6 +/- 0.2 |

Microbial Load Evaluation:

Manufactured lot has been statistically sampled. Samples were acceptable for microbial content and aesthetic value following a minimum of 72 hours at 33-37°C.

Signed



Quality Assurance Supervisor