

Certificate of Quality

Product Name: VERSATREK MYCO GS **Lot Number:** 976700 **Product Number:** 7112-42 **Expiration Date:** 2022-05-04

(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	Performance Criteria
Mycobacterium fortuitum	6841	Positive in \leq 14 Days
Mycobacterium intracellulare	13950	Positive in \leq 14 Days
Mycobacterium kansasii	12478	Positive in \leq 14 Days
Mycobacterium scrofulaceum	19981	Positive in \leq 14 Days
Mycobacterium tuberculosis	25177	Positive in \leq 14 Days

Product was tested in the Versatrek system as documented in the instructions for use.

Physical Characteristics:

Appearance: Light Amber, Clear Broth w/ No Precipitate

pH @ 20-25°C: 6.8 +/- 0.2

Microbial Load Evaluation:

Manufactured lot has been statistically sampled. Samples were acceptable for microbial content and aesthetic value following a minimum of 7 days at 20-25C and 33-37C.

Signed

Quality Assurance Supervisor