

Certificate of Quality

Product Name: CAMHB W/LHB, MANUAL, 11ML, 10/BOX, IVD **Product Number:** CP112-10 **Lot Number:** 278763 **Expiration Date:** 2025-09-30

(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

Streptococcus pneumoniae 49619 MIC limits are within CLSI specifications

Physical Characteristics:

Appearance: Red, Clear Broth w/ No Significant Precipitate

pH @ 20-25°C: 7.3 +/- 0.1

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

Senior Quality Assurance Engineer