

Certificate of Quality

Product Name: NAC Attack BTLx5/50ml
Lot Number: 225115

Product Number: R210250
Expiration Date: 2019-01-10

(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 Criteri
Staphylococcus epidermidis	12228	No Growth
Escherichia coli	25922	No Growth
Proteus mirabilis	12453	No Growth
Streptococcus sanguinis	10556	No Growth
Neisseria sicca	9913	No Growth

Product was challenged with strains to simulate the decontamination process associated with specimen processing. Product was identified as acceptable if bacteria were destroyed, i.e. no bacteria were recovered.

Physical Characteristics:

Appearance: NAC Powder: White, Crystal Powder

TB Base: Colorless, Clear Liquid

pH @ 20-25°C: N/A

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