



Certificate of Quality

Product Name: BactiStaph Latex 150TST/KT
Lot Number: 856913

Product Number: R21144
Expiration Date: 2012-01-04
(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 Quality Control specifications and were found to meet performance criteria for this product.

Organism Challenge

Staphylococcus aureus (3 strains*)
Coagulase (-) Staphylococcus (3 strains)
Positive Control
Negative Control

Performance Criteria

(+) Agglutination
(-) Agglutination
(+) Agglutination
(-) Agglutination

* 1 = MRSA

Physical Characteristics:

Appearance: Black Liquid
pH @ 20-25°C: N/A

Microbial Load Evaluation:

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

A handwritten signature in black ink, appearing to read "S. Kendall", written over a horizontal line.

Quality Control Manager